# EXHIBIT 1

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

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| IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION | MDL No. 2741<br><br>Case No. 16-md-02741-VC |
| This document relates to:<br>*Hardeman v. Monsanto* (3:16-cv-525),<br>*Stevick v. Monsanto* (3:16-cv-2341), and<br>*Gebeyehou v. Monsanto* (3:16-cv-5813) | |

# EXPERT REPORT OF

# DR. CHARLES BENBROOK

# EXPERT REPORT OF CHARLES M. BENBROOK, PhD

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## I. Summary of Opinions

1. I have been asked by the Plaintiffs' attorneys to review materials relating to the composition, use, testing, stewardship, risk assessment, and regulation of glyphosate and Roundup®-brand herbicides ("Roundup"). My review of public documents, the discovery record, and my work over decades on glyphosate risks, regulation, and the use of Roundup herbicides have shaped the opinions expressed herein.

2. All of my opinions were reached to a reasonable degree of scientific certainty.

3. I include opinions in this summary section most responsive to the key issues I have been asked to address. These opinions cover many different areas, but they relate to my core expertise of examining whether Monsanto's conduct as a pesticide manufacturer and registrant, comport with its obligations and stewardship responsibilities.

4. Throughout this report, additional opinions, and more complete explanations of my opinions are presented, along with my discussion of the various Monsanto actions, inactions, documents, and initiatives leading to my opinions.

5. I reserve the right to augment or revise this report to fix typos, add MONGLY document references, or incorporate new studies or data I become aware of that alter or reinforce findings and opinions expressed in this report.

6. The likelihood that exposures to Roundup can trigger or contribute to the progression of non-Hodgkin lymphoma is central to this case. Extensive scientific and regulatory resources have been invested over decades in pursuit of clarity on this core question. Has Monsanto done everything it could have, and should have done to resolve uncertainty in the scientific data relied upon to answer this core question?

   a. In my opinion, no, they have not.

b. The first valid chronic oncogenicity study on glyphosate was submitted to EPA in 1983 (the Bio/dynamic mouse study). It showed an increase in renal tubular adenomas in the male mice that Monsanto claimed was not treatment related. EPA disagreed, and classified glyphosate as a "possible human oncogen" in 1985.

c. Monsanto challenged EPA's determination through multiple avenues, for years, leading to an EPA request for Monsanto to do a new and better study. A Scientific Advisory Panel convened by EPA to provide guidance in resolving the controversy over the 1983 Bio/dynamic study called for a repeat study. The EPA adopted the SAP's advice and required a repeat mouse study in its 1986 Registration Standard document on glyphosate. Monsanto refused to conduct it and has not done so to this day.

d. Monsanto has refused since the mid-1980s to conduct the studies needed to resolve uncertainty over the oncogenicity of Roundup, including studies specifically requested by the EPA. In my opinion, the failure of Monsanto to invest in new and better science, such as the more powerful mouse cancer replacement study requested by EPA in 1986, has perpetuated scientific uncertainty and undermined EPA's ability to understand and quantify Roundup cancer risks.

e. I also conclude that, as a result, the EPA has been unable to determine whether Roundup-associated cancer risks fall below or exceed the agency's "level of concern." Because no one has ever sprayed or been exposed to pure glyphosate, Monsanto's assertions and EPA's conclusion

that glyphosate does not pose significant cancer risk to the general public, based on current and typical levels of exposure, is not reassuring nor particularly useful in understanding and managing cancer risks arising from exposures to formulated Roundup and other GBHs.

f. Dr. Donna Farmer, a senior Monsanto scientists wrote to a Monsanto communications professional "You cannot say that Roundup is not a carcinogen…we have not done the necessary testing on the formulation to make that statement. The testing of the formulations are not anywhere near the level of the [testing on] the active ingredient." (MONGLY00922457-8).

7. For decades, there have been multiple studies showing that formulated Roundup is more toxic than pure, 100% technical glyphosate. Most of the surfactants in Roundup-brand herbicides are more toxic, ounce for ounce, than glyphosate. Plus, pure glyphosate does not move readily through the skin or into cells, whereas Roundup and other GBHs does.

a. The surfactants in Roundup products are added to formulations to speed up the movement of glyphosate through weed leaf surfaces, and then into the cells of weeds. Roundup surfactants act roughly the same way when Roundup comes into contact with human skin. This is one of the primary reasons why Roundup is markedly more toxic to exposed humans than glyphosate.

b. Despite knowledge of the differences in toxicity and risks arising from exposures to formulated Roundup in contrast to pure glyphosate, Monsanto has not carried out critical, long-term cancer feeding studies

with Roundup. Nor has anyone else.

c. In my opinion, Monsanto's refusal to carry out long-term cancer feeding studies in both mice and rats using a common Roundup formulation has perpetuated scientific uncertainty and delayed the regulatory consequences of such studies, in the event one or both studies report evidence of a treatment-related oncogenic response.

8. Monsanto has refused to conduct state-of-the-art genotoxicity assays in mammals and in human populations exposed to formulated Roundup. When the EPA reviewed this area of science, my systematic review of the studies cited and available to the EPA reveals that those studies originated by industry, and for the most part conducted by Monsanto, generally show no genotoxic effect, whereas independent studies, utilizing more advanced state-of-the-art systems, do show genotoxic effect. This discrepancy indicates that the EPA's review of genotoxicity has been skewed by industry studies that are less sensitive.

a. In its September 2016 evaluation of glyphosate oncogenicity, EPA reviews about 50 registrant-commissioned genotoxicity studies carried out mostly by Monsanto on pure, glyphosate technical. Only one of these ~50 registrant studies reported evidence of a genotoxic response.

b. Another approximate 45 registrant-commissioned studies were carried out on formulated Roundup and other GBHs. Of the ~45 registrant studies on GBH genotoxicity, none reported evidence of a genotoxic response.

c. Accordingly, out of nearly 100 registrant-commissioned studies cited in EPA's September 2016 report on glyphosate genotoxicity, only one reported a positive genotoxic response.

d. About another 55 studies on pure glyphosate have been published in peer-reviewed science journals (hereafter referred to as "public literature"), and another 70 have been published on formulated GBHs. Of these ~125 studies in public literature, about 85 reported one or more positive genotoxic responses, or about 70%.

e. In my opinion, the remarkable disparity in the results of registrant-commissioned genotoxicity studies, in contrast to those done by mostly academic scientists, arises in large part from the use of relatively newer and more sensitive assay systems by academic scientists. The body of my report presents further empirical data and observations on the likely reasons why such disparate results are reported in registrant studies versus public literature studies.

9. Additionally, I conducted a detailed analysis of the studies relied on by the EPA in its genotoxicity assessment as reported in its September 2016 report, compared to the studies relied upon by IARC in its 2015 assessment of the genotoxic and oncogenic potential of glyphosate and GBHs. IARC relied on about 120 published studies in peer-reviewed journals, of which EPA cited only 50 (~42%). The basis of this analysis is described in Appendix C.

a. IARC placed heavy weight on three studies of human populations exposed to GBHs that displayed, according to the IARC Working Group, strong evidence of direct damage to human DNA, while EPA did not place much, if any, weight on these three positive studies, because, according to EPA, its assessment was focused on studies testing the genotoxicity of glyphosate technical, not studies on Roundup or other GBHs.

b. In my opinion, studies on the genotoxic effects of formulated GBHs are significantly more important and relevant to human health-risk assessments than studies on pure glyphosate. I also conclude that EPA's admitted failure to seriously assess the approximate 70 public literature studies on the genotoxicity of formulated GBHs is why the agency errantly determined that "glyphosate" is likely not genotoxic. EPA might actually be correct in that judgement, but no one sprays pure glyphosate, and strong evidence points to the genotoxicity of formulated GBHs.

c. The most recent genotoxicity studies cited by the EPA and IARC in their respective reports were published or dated 2014, with the exception of one 2015 study by Marquez et al (2015) assessing DNA damage in an European eel species that was cited by both EPA and IARC. I conducted a PubMed search for genotoxicity studies on glyphosate and GBHs on November 19, 2018 and identified 26 studies published since 2015, of which 25 reported positive evidence of genotoxicity in one or more assays. Twelve mammalian studies were all positive, including evidence of oxidative stress in three assays in human cells and DNA damage in five assays.

d. I conclude that the scientific studies published since the EPA and IARC reports has added to the strong evidence supporting the genotoxicity of glyphosate and GBHs through each of the two mechanisms of action highlighted in the 2015 IARC report.

10. In 1999, Monsanto hired Dr. James Parry, a world-renowned genotoxicity expert,

to advise the company on what steps it should take to better understand and respond to public literature studies reporting evidence of a genotoxic response following exposures to glyphosate and/or a GBH. Dr. Parry provided Monsanto 11 specific recommendations for further genotoxicity research. Monsanto refused to conduct new studies in 9 of the 11 areas.

a. In my opinion, Monsanto's failure to conduct the state-of-the-art genotoxicity assays on formulated GBHs that Dr. Parry recommended is a primary reason why the EPA, as opposed to IARC (which did rely on the published state-of-the-art studies), concluded that glyphosate poses no significant genotoxic risk to humans.

b. Rather than conduct the more sophisticated genotoxicity assays recommended by Dr. Parry, Monsanto instead commissioned members of its Third-Party Network of glyphosate-friendly scientists (discussed below) to write and publish review articles arguing that evidence of genotoxicity in public literature studies is the result of flawed study designs, excessive dose levels, inappropriate routes of administration, overt toxicity, or other technical problems. Substantial portions of three of these reviews were ghost-written by Monsanto scientists not listed among the co-authors.

c. Recent genotoxicity studies—again performed by independent scientists—continue to show clear genotoxic responses.

11. In 1985, the Office of Pesticide Programs classified glyphosate as a "possible human oncogen" as a result of the renal tubular adenomas in the 1983 Bio/dynamics mouse study. In my opinion, by or about 1986, Monsanto could have and should have added a warning

to Roundup labels alerting applicators that heavy and/or sustained exposures to Roundup might contribute to the risk of certain cancers. Similar information and warnings should have been included in chemical safety data sheets, applicator training materials, and the information supplied to operators at poison control centers fielding calls from people concerned over the health risks stemming from a high-exposure episode.

12. The 1986 glyphosate Registration Standard document issued by the EPA required Monsanto to add several commonsense worker-safety provisions onto Roundup product labels (e.g., wear gloves, chemical resistant shoes, and goggles or a face shield when applying Roundup; discard cloths that are drenched; wash clothes separately from other laundry). Monsanto refused to add the majority of these provisions to their product labels. In my opinion, Monsanto failed to live up to its stated commitment to product safety in its refusal to add such simple, commonsense worker-safety provisions to Roundup labels.

13. Registrants bear the primary responsibility to assure that there will be no "unreasonable adverse effects on man or the environment" when the pesticide is used in accord with label directions and requirements. In my opinion, Monsanto has failed to meet this obligation by failing to warn about the risks of oncogenicity, genotoxicity, and most recently, carcinogenicity. For example -- the Office of Environmental Health Hazard Assessment (OEHHA) in California issued a Proposition 65 Warning and factsheet in 2018 entitled "Glyphosate" that states "Glyphosate is on the Proposition 65 list because it has been identified as a carcinogen." Significantly, in response to "How can I reduce my exposure to glyphosate?", OEHHA writes "Do not handle or use glyphosate herbicides without skin protection, such as gloves." Monsanto, however, has never advised applicators to wear gloves, and denied an EPA request that such a requirement be added to Roundup labels.

14. In recent years, glyphosate-based herbicide applications made using hand held, backpack, ATV, or truck- mounted sprayers likely account for around 3% of total use in the U.S., and a disproportionately high share of the worker-safety poisoning and illness episodes reported to and/or investigated by regulatory authorities or physicians.

a. Applicator exposures, and hence risk, are a function of: (a) how many days in a year, and how many hours per day a person sprays Roundup; (b) the spray dilution, length of the spray wand, the pressure and pattern of the spray, (c) how the applicator directs the spray, and wind conditions, and (d) the degree to which applicators abide by label directions and are diligent -- or careless -- in their efforts to minimize exposures.

b. Even among diligent applicators, high-exposure episodes will occur when, for example, a hose leaks, a fitting becomes loose, concentrated herbicide spills onto skin or clothing, and/or when cleaning, servicing, or repairing spray equipment.

c. In my opinion, since the 1980s, individuals applying Roundup via handheld, backpack, ATV, and truck-mounted sprayers have faced, and continue to face markedly higher exposures and risks, especially on windy days, and that on some days, circumstances will arise that lead to high or very-high exposures, compared to "typical" conditions.

d. Likewise, I conclude that since the 1980s, farmers and commercial applicators of Roundup spraying farm fields are also sometimes exposed to much higher levels of Roundup than "normal," when dealing with plugged nozzles, filling or cleaning spray tanks, fixing leaks, repairing

equipment, and handling and transferring concentrated herbicide.

15. In my opinion, Monsanto has failed to adequately provide guidance to mixer-loaders and applicators regarding steps they should take to first, prevent very-high exposure episodes, and second, what they should do in the event of a high-exposure episode to limit personal risk and respond to any signs of ill effects.

a. Regardless of when, where, and how Roundup is applied, mixer-handler and applicator risk is also clearly determined to a significant degree by the number of days per year an individual handles and sprays Roundup, coupled with the average hours per day the person is applying the herbicide.

b. On Roundup labels and in Monsanto-sponsored educational and promotional materials, there is no information explaining that applicator risks rise with frequency of use and cumulative hours during which herbicides are sprayed in a given year. No information or guidance is offered to applicators to help prevent and mitigate high-exposure circumstances like hose leaks, equipment problems, or erratic wind patterns.

16. Monsanto has an operational goal called "Freedom to Operate," which aspires to limit any restrictions on Monsanto's ability to freely sell and market glyphosate-based herbicides, including even commonsense worker-safety provisions. In my opinion, Monsanto's zeal in protecting glyphosate's FTO directly conflicts with health-protection obligations imposed by federal law and the stewardship responsibilities of a pesticide manufacturer with a stated commitment to product safety.

17. At several stages in the regulatory history of glyphosate and Roundup-brand herbicides, this report documents episodes in which, I conclude, Monsanto failed to meet obligations imposed on it by federal law and EPA regulations.

18. I conclude that Monsanto actions, and in some cases inaction, undermined incremental progress in EPA toward more accurate and realistic worker-risk assessments, and precluded commonsense steps to reduce exposures, and hence risk, among Roundup users.

19. In my opinion, Monsanto actions and inaction blocked or avoided the communication to users of the need for effective and simple worker-safety provisions. I also conclude that the absence of such worker-safety provisions, the absence of warnings of possible health effects, and the systematic downplaying of Roundup's toxicity has markedly increased exposures and cancer risk levels for many users.

20. In my opinion, Monsanto has underperformed in its efforts to discourage clearly false information and dangerous assertions regarding Roundup toxicity and risks made by individuals speaking on its behalf. Two common assertions that have perpetuated a lack of care by some people applying Roundup herbicides are that Roundup is "non-toxic" and "safe enough to drink."

21. In my opinion, substantial questions persist over the levels of known, oncogenic impurities and breakdown products in Roundup and other GBHs. Additional monitoring and research is urgently needed to better understand the contaminants in various GBHs, where they come from, and how they have changed over time. I believe Monsanto was obligated to conduct that testing as part of its ongoing stewardship obligations, but I am not aware of such data being submitted to the EPA, nor providing a basis for more accurate human-health risk assessments.

22. But it is also my opinion that the primary focus of pesticide safety educators,

Roundup applicators, regulators, and the court in this litigation should be the potential contribution of formulated Roundup and other GBHs to human illness, regardless of whether an adverse biological response in an exposed individual comes from the way the glyphosate was made, the surfactants added into the GBH applied, or chemical reactions that occur after the spraying of a GBH, including reactions that can occur inside the human body.

## II. Science Judgements Impacting the Use of Glyphosate

23. Various terms are used to refer to the potential of a chemical to cause cancer. The term "carcinogenic risk" used in the Monograph series issued by IARC means that "an agent is capable of causing cancer."

24. In this report, I follow standard practice in EPA and the toxicology community. The word "oncogen" refers to a chemical thought to cause benign or malignant tumors in animals or humans; the term "carcinogen" refers to a chemical thought to cause malignant tumors in animals or humans.

25. The Toxicology Branch within the EPA's Office of Pesticide Programs (OPP) decided that glyphosate should be classified as a possible human oncogen in 1985. This decision posed a significant economic threat to Monsanto, as stated by Frank Serdy, Monsanto's Manager of Federal and State Regulatory Affairs in his March 13, 1985 letter to the OPP Registration Division Director, Doug Campt.

26. In the 1980s, once glyphosate was classified as a potential oncogen, any significant, future expansion in agricultural use of Roundup herbicides would require the establishment by EPA of food-additive tolerances to cover the glyphosate residues that would be present in certain fractions of grains and oilseed crops. Such tolerances can be established pursuant to Section 409 of the Food, Drug, and Cosmetic Act (FDCA).

27. But glyphosate-related Section 409 petitions in the EPA pipeline, and any future Section 409 tolerance petitions, would be blocked by the anti-cancer Delaney Clause, which was then part of Section 409 in the FDCA.

28. The Delaney Clause prohibits the knowing addition to food of cancer-causing food additives. When pesticide residues concentrate in certain foods (e.g. ketchup) or food ingredients (wheat bran), they are considered a food additive by the EPA. Hence, from the late 1970s through 1996, EPA generally did not approve Section 409 tolerance petitions for pesticides classified by the agency as possible, probable, or proven oncogens. (The 1986 NAS report *Regulating Pesticides in Food: The Delaney Paradox* contains a detailed explanation of how and why the Delaney clause was then impacting the tolerance-setting process).

**2. Failure to Repeat 1983 Mouse Oncogenicity Study**

29. A contract laboratory called Bio/dynamics conducted a Monsanto-commissioned mouse oncogenicity study in the early 1980s. The study was needed to fill an important, glyphosate chronic toxicology datagap. The study results were submitted to EPA in 1983. The EPA's preliminary review of the study concluded that glyphosate had caused a dose-related increase in renal tubule adenomas in male mice, a rare kidney tumor, and as a result was classifiable under then-current EPA cancer guidelines as a possible human carcinogen.

30. This EPA determination contradicted the Bio/dynamics interpretation of the results, as well as Monsanto's. Conflicting interpretations of this study set the stage for a conflict between Monsanto and the EPA that lasted several years.

31. To gain approval of the many, new Section 409 tolerances that would be needed to add new crops to Roundup product labels, the company ***had to reverse*** the Office of Pesticide Programs' (OPP) "possible oncogen" classification of glyphosate.

32. When such disagreements arise over the interpretation of a specific study, the routine response by OPP/EPA is to require the registrant to conduct a new, and hopefully more sensitive study. And so, OPP required Monsanto to conduct a new, much more powerful (statistically) mouse oncogenicity study.

33. Monsanto responded to EPA's request by arguing no such study was needed. OPP/EPA responded by stating why it felt such a study was indeed essential.

34. Eight years of Monsanto-EPA debate ensued over this 1983 mouse study. At multiple points, Monsanto found ways to raise new scientific issues in need of exploration with OPP scientists, prior to a final OPP decision on whether the 1983 Bio/dynamics study was positive or negative for cancer, and whether it needed to be repeated.

35. Monsanto demonstrated both its ability and willingness to direct political pressure on the agency. The company's influence in Congress, and at senior levels in Executive Branch agencies, made it possible for Monsanto to incrementally raise the stakes facing the OPP, until OPP brought its evaluation of the Bio/dynamics study into alignment with Monsanto's.

36. In 1991, EPA changed its interpretation of the 1983 Bio/dynamics mouse oncogenicity study, largely on account of one additional tumor in control-group mouse #1028. This tumor was found by a pathologist that Monsanto had hired to reread the study's kidney slides.

37. All of the EPA pathologists that had reviewed the Bio/dynamics mouse kidney slides could not see, and did not agree that there was a renal tubular adenoma in the kidney of control mouse #1028.

38. Each of the pathologists paid by Monsanto to assess the kidney slides concurred that there was a renal tubular adenoma in control mouse #1028, ***except*** for the pathologist working for Bio/dynamics when the kidney slides from the study were initially read.

39. This pathologist (Dr. McConnell) reported no renal tubule adenoma in control mouse #1028, nor in any other control male mouse. Years later, after re-reading the kidney slides, this pathologist changed his mind and agreed with the other Monsanto-hired pathologists, who did see a renal tubular adenoma in control mouse #1028.

40. Despite multiple EPA requests, Monsanto still has not conducted a new mouse oncogenicity study. Monsanto also refused to carry out a follow-up study that EPA and Monsanto scientists designed collaboratively, in the hope of resolving lingering issues over the presence of renal tubular adenomas in the 1983 Bio/dynamics study.

41. In my opinion, Monsanto's refusal to conduct the new oncogenicity studies in mice requested by the EPA in the late 1980s altered the regulatory history of glyphosate and Roundup herbicides. Had at least one of the requested studies been completed and showed no oncogenic response, the debate over the 1983 Bio/dynamic mouse study would have ended and EPA would likely have downgraded its classification of glyphosate oncogenicity. This eventually happened in 1991, but without the benefit of a new mouse oncogenicity study.

42. If a new mouse oncogenicity study had reported a positive response for renal tubular adenomas, and/or other tumors, the EPA's "possible oncogen" classification would have remained in place, or possibly been upgraded to "probable." I also conclude that this later scenario would have markedly restricted the range of new crop and weed control uses added onto Roundup-brand herbicide labels beginning around 1990, and led to the addition of new warnings and worker-safety provisions on most, if not all Roundup labels.

**3. Negative Genotoxicity Studies Give Rise to a False Sense of Safety**

43. The first round of mutagenicity and genotoxicity studies on glyphosate were commissioned by Monsanto in the 1970s, conducted by IBT, and were found to be invalid and/or fraudulent. The second round was done in the early 1980s, and fulfilled the then-existing OPP mutagenicity and genotoxicity data requirements.

44. The laboratories conducting these cell-assay studies in the 1980s on pure glyphosate for Monsanto reported no evidence of mutagenic or genotoxic effects, and EPA scientists accepted this determination. Since the early approvals of Roundup herbicide labels in the 1970s and through multiple re-assessments over the last 40 years, the EPA has stuck with its original determination that glyphosate technical (i.e. nearly pure, 100% glyphosate) is not genotoxic in humans via oral ingestion, at levels of exposure typically expected in the food supply.

45. EPA's initial genotoxicity determination played a central role in the successful effort by Monsanto to change OPP's mind on the results of the disputed, 1983 Bio/dynamics mouse oncogenicity study.

46. On multiple occasions since the 1980s, the purported absence of evidence of genotoxicity has been cited by Monsanto and the EPA as an important reason to discount other evidence of toxicity, including cancer risk, following exposure to glyphosate-based herbicides.

47. But in my opinion, based on the composition of formulated, glyphosate-based herbicides (GBHs) sold by Monsanto since the early 1980s, Roundup had almost certainly always been genotoxic. In 2015, the International Agency for Research on Cancer (IARC) concluded that there is "strong evidence" that GBHs are genotoxic through at least two genotoxic mechanisms known to be associated with cancer in humans.

48. In my opinion, the fundamental flaw in EPA's assessment of Roundup genotoxicity has been, and remains, the agency's near-sole focus on genotoxicity tests following exposure to pure, glyphosate technical, rather than exposure to the formulated products actually sprayed by people, and to which people are exposed.

49. EPA justified its approach to genotoxicity testing on the basis of a flawed assumption -- that the "inert" ingredients used in the formulation of Roundup herbicides were, indeed, inert biologically, and therefor posed no genotoxic risk.

50. The first evidence suggesting that glyphosate or glyphosate-based herbicides could trigger genotoxic responses appeared in the scientific literature in the 1990s.

51. By 2003, there was considerable evidence in peer-reviewed science journals suggesting that at least certain glyphosate-based herbicides (GBHs) were genotoxic, a conclusion concurred with by Dr. Parry, a leading genotoxicity expert hired by Monsanto as a consultant.

52. IARC found "***strong evidence***" of glyphosate and GBH genotoxicity in its 2015 assessment, highlighting two genotoxic mechanisms that can lead to cancer.

53. The record makes clear that Monsanto was reluctant to test their formulated glyphosate-based herbicides for both genotoxicity and cancer.

54. Dr. James Parry was hired by Monsanto to help the company evaluate published studies suggesting a genotoxic response following exposure to glyphosate and/or GBHs. After his reviews of multiple published and proprietary Monsanto genotoxicity studies, Dr. Parry recommending that Monsanto carry out new studies in about a dozen areas.

55. Rather than sponsor the genotoxicity studies that Dr. Parry had recommended, Monsanto commissioned glyphosate-friendly scientists to review and summarize the then-existing, glyphosate genotoxicity database.

56. Since the 1990s, Monsanto has commissioned at least four purportedly "independent" scientific reviews on the genotoxicity of glyphosate and/or glyphosate-based herbicides. Each one concludes there is no credible evidence to suggest glyphosate or formulated, Roundup herbicides pose a significant genotoxic risk.

## D. Differing EPA and IARC Assessments of Glyphosate Genotoxicity

57. EPA's in-depth, post-IARC risk assessment of glyphosate was entitled "Glyphosate Issue Paper: Evaluation of Carcinogenic Potential" and is dated September 12, 2016. It contains the EPA's detailed assessment of genotoxicity studies conducted on glyphosate technical, and restates its long-held position -- "The overall weight of evidence indicates there is no convincing evidence that glyphosate induces mutations *in vivo* via the oral route" based on current, labeled uses and typical, expected exposures.

58. The EPA also explains in this September 2016 report that it's detailed assessment is limited to genotoxicity studies on glyphosate technical, and that the agency is waiting for the completion of ongoing work by the National Toxicology Program (NTP) on formulated GBH genotoxicity prior to reaching a judgement on differences in the genotoxicity of pure, technical glyphosate, in contrast to GBHs.

59. In its March 2015 paper reporting the "probably carcinogenic to humans" classification of glyphosate and GBHs, the IARC Working Group highlighted "strong evidence" of genotoxicity as an important factor supporting its ultimate "probably carcinogenic to humans" classification. The basis for IARC's glyphosate classification, and the genotoxicity studies reviewed by the Working Group, are described in detail in the IARC Monograph 112 volume initially released on July 29, 2015.

60. The mutagenicity and genotoxicity studies and assays cited and relied upon by the EPA and IARC differ significantly, as evident in my analysis of the genotoxicity-related tables in the EPA and IARC risk-assessment documents. The data sources and methods used in my analysis are summarized here, and described more fully in Appendix C. One important point to note -- several studies report the results of multiple assays, while others report results on both glyphosate technical and formulated GBHs. For this reason, the number of "positive" versus "negative" assay results recorded in the EPA and IARC tables exceeds the number of studies cited.

**1. Studies Relied Upon by EPA and IARC**

61. Pages 99-125 of the 2016 EPA glyphosate oncogenic risk assessment discuss studies on "Gene Mutations" involving technical (i.e. near 100% pure) glyphosate. Seven tables in this section identify the specific, mostly regulatory studies on glyphosate technical that were considered by EPA, and reports whether the study presented data positive for one or more genotoxic responses, or were negative for genotoxicity.

62. The IARC Monograph report has a similar set of tables assessing roughly the same categories of genotoxicity studies addressed in the EPA report, plus four types of studies not considered by EPA (exposed humans, human cells *in vitro* - AMPA, non-human mammals *in vivo* - AMPA, and non-mammalian systems *in vivo* - AMPA). Like the EPA report, the IARC Working Group also identifies whether a given study was positive or negative for evidence of genotoxicity. But unlike EPA, the IARC Working Group reviewed mostly studies in peer-reviewed journals in each category on glyphosate technical ***and*** formulated GBHs.

63. Of the approximate 120 genotoxicity studies in all categories cited by IARC, EPA cited about 50 in its 2016 report, or about 42% of those considered by IARC.

64. Of the ~120 studies reviewed by IARC, ~55 fell in mammalian test categories, and are most relevant to assessment of glyphosate's potential to trigger human cancer through a genotoxic mechanism of action. EPA considered abut 40 of these studies, or about 75% of the number reviewed by IARC.

65. Of the five studies on "Exposed Humans" reviewed by the IARC Working Group, three were regarded as positive. These studies were given little or no weight by EPA because they entailed exposures to formulated GBHs, not technical glyphosate (the focus of EPA's review).

66. IARC reviewed five studies classified as "Oxidative Stress Human Cells *in vitro* - Glyphosate," of which four were positive. EPA considered just one of these studies (the positive Mladinic et al [2009b] study).

67. I conducted an analysis of the outcome of the glyphosate and GBH genotoxicity studies conducted or commissioned by Monsanto or other registrants, in contrast to studies carried out by scientists not working on behalf of a GBH registrant and who published their study results in peer-reviewed journals.

68. All regulatory studies cited in the September 2016 EPA report or in a Monsanto-commissioned genotoxicity review article were analyzed relative to "positive" or "negative" results. Likewise, all studies published in peer-reviewed journals that were cited by EPA and/or the IARC Working Group were analyzed, along with whether they reported "positive" or "negative" genotoxicity results.

69. Genotoxicity studies were listed in the seven categories the EPA used to organize the glyphosate-technical genotoxicity studies the agency reviewed. The results of registrant-

commissioned regulatory studies in each category were compared to the results of studies published in peer-reviewed journals (public literature).

70. A total of 106 studies on glyphosate technical were identified. Of these, 52 were regulatory studies and 54 were published in science journals.

71. Of the 52 regulatory studies assessing the genotoxicity of glyphosate technical, only one reported a positive result (an *in vivo* bone marrow micronucleus study), while 35 of the public-literature studies reported positive evidence of genotoxicity.

72. In the case of studies assessing the genotoxicity of formulated GBHs, registrants conducted 44 studies cited by the EPA and/or in a Monsanto-commissioned review article, and another 70 were published in science journals, for a total of 114.

73. Across the total 114 genotoxicity studies on formulated GBHs, none of the regulatory studies reported evidence of a genotoxic response, compared to 51 (73%) of the public-literature studies.

74. A review of the date when registrant-commissioned, genotoxicity studies were conducted, compared to when public literature studies using the same assay system were conducted, is revealing.

75. In terms of *In vivo* chromosomal aberration studies on glyphosate technical, the most recent registrant study was completed in 1994, while two of three public literature studies were done in 2012. In the case of the same type of study on formulated GBHs reported in public literature, seven out of eight assays were completed in the 2005-2011 (five positive), while no such study on GBHs was carried out by registrants.

76. The 15 *In vivo* micronuclei assays carried out by registrants on GBHs were done during or before 2011, all negative. Five of 16 public literature studies were done from 2011 through 2013 (all positive).

77. In terms of glyphosate technical assays exploring DNA damage in humans, only two, negative registrant studies were completed, one in 1978 and the other in 1982. The public literature contains studies reporting the results of 20 assays conducted since 2004, 18 of which reported one or more positive result.

78. In my opinion, assays designed to detect direct damage to DNA in humans following exposure to a ***formulated GBH*** are the most important in evaluating glyphosate and GBH genotoxicity. In 2001, Monsanto conducted one direct DNA damage study on a GBH formulation, MON 35050. It reported no evidence of oxidative stress in liver or kidney cells. The public literature reports the results of 32 direct DNA damage assays since 2005, of which 27 have reported one or more positive responses.

79. Based on the above analysis, I conclude that the dramatic differences in the results of genotoxicity assays reported in registrant-sponsored studies, in contrast to assay results appearing in peer-reviewed journals, arise from the state-of-science when various studies were conducted, coupled with the generally more sensitivity assay systems used by the scientists publishing their results in peer-reviewed journals.

**2. Monsanto's Response to Dr. Parry's Recommendations**

80. Dr. Parry provided 11 specific recommendations to Monsanto, following his review of several published and Monsanto-commissioned genotoxicity studies. Additional testing of technical glyphosate was called for in four areas, while seven areas of new testing were recommended in the case of formulated GBHs.

81. In one of the four areas of testing of technical glyphosate, Monsanto carried out seven tests, each designed to confirm, refute, or explain the findings in the positive *in vivo* bone marrow micronucleus study conducted Bolognesi et al (1997). No new studies were conducted in the other three areas Dr. Parry had recommended.

82. In addition, Dr. Parry placed low priority on additional studies of glyphosate technical using Bacterial reverse mutation assays in light of the more than two-dozen negative Bacterial reverse mutation regulatory studies that had already been conducted. Since delivery of Dr. Parry's report to Monsanto, more than a dozen new, Bacterial reverse mutation studies have been done by registrants on glyphosate technical.

83. Dr. Parry emphasized, in particular, the need to conduct more thorough and more sensitivity testing of formulated GBHs. In the seven areas of testing recommended by Dr. Parry on GBHs, Monsanto carried out 15 tests in just one area -- Bacterial reverse mutation studies.

84. I conclude that Monsanto's failure to test formulated Roundup herbicides for genotoxicity, as recommended by Dr. Parry, is a primary reason why the EPA and other regulatory authorities have failed for decades to recognize the potential for glyphosate-based herbicides to increase the risk of cancer, including risk of NHL, via a genotoxic mechanism of action.

85. It is my opinion that the absence of a single, well-designed chronic feeding oncogenicity study in mice or rats exposed to formulated glyphosate-based herbicides, rather than pure glyphosate technical, is the most important single gap in the existing scientific appraisal of the human-health risks stemming from use of, and exposure to Roundup and other glyphosate-based herbicides.

86. I conclude that Monsanto should have, and could have conducted such a study in the 1990s, and that over time the scientific need for such a study has grown stronger in step with the growing number and diversity of positive glyphosate and GBH genotoxicity studies, coupled with suggestive evidence of a link between GBH use and exposures and non-Hodgkin lymphoma in multiple epidemiological studies.

87. Last, in my opinion, the failure of EPA to require Monsanto, or any other GBH registrant, to carry out a chronic oncogenicity feeding study using a formulated GBH does not obviate the scientific importance and regulatory risk-assessment relevance of such a study. It also does not relieve Monsanto of its obligation, as the dominant manufacturer of GHBs, to carry out such a study in the interest of assuring its formulated products are as safe as the company had been claiming since the late 1970s.

88. The primary goal driving Monsanto's herbicide business is opening up new markets for Roundup-brand products (i.e., gaining new registrations), and minimizing any possible restrictions on the potential sale of Monsanto products already on the market.

89. Actions aimed at achieving these goals are often referred to inside Monsanto as preserving glyphosate's "Freedom to Operate" (FTO).

90. Monsanto reached out to and systematically used a network of independent scientists in conducting a variety of efforts to protect glyphosate's FTO.

91. The goal of Monsanto's engagement with independent scientists was succinctly stated in an internal, May 26, 1999 email. The goal is to encourage "… people to get up and shout Glyphosate is Non-toxic." (MONGLY00904009)

92. "Non-toxic" is not an accurate description of glyphosate or Roundup herbicides. Yet through advertising, promotional material, and messaging advanced by sales staff, Monsanto

invested significant effort and resources in a sustained effort to convince the general public that Roundup is "safe" because it is "non-toxic."

**1. Monsanto's Third Party Network of Experts**

93. Monsanto made heavy use of supposedly independent scientists in its "Scientific Outreach" (SO) and PR campaigns in support of the safety of glyphosate and Roundup-brand herbicides. In some instances, such individuals were appointed to an ad hoc, or standing advisory committee or panel. In other cases, they simply worked on a fee-for-service basis on a defined task.

94. Many of these glyphosate-friendly, consulting experts had once worked for Monsanto. Many have authored or co-authored one to several papers commissioned and paid for by Monsanto. Most of these papers contained passages ghost-written by Monsanto scientists, and some were largely ghost-written by Monsanto. "Ghost-writing" refers to contributions to a written document by a person not listed as the author, or among the co-authors of the document.

95. In addition, Monsanto frequently asked and/or sponsored glyphosate-friendly experts to:

- Present oral and/or written comments to regulatory agencies, or their advisory groups;
- Make presentations to allied industry groups, academics, or professional society meetings; and
- Assist in gaining positive media coverage of glyphosate health issues.

96. Several examples of the roles, activities, and contributions of glyphosate-friendly scientists are described in the body of this report, but there are far too many instances and individuals involved to provide a comprehensive accounting of Third Party Network activities.

97. Based on my review of records in this case, I am struck by the scope of Monsanto's efforts to utilize supposedly independent scientists to: (1) restate company positions

and scientific conclusions, (2) influence and contribute to the literature in peer-reviewed, science journals, (3) shape the information accessible to regulators, and (4) reinforce and/or amplify Scientific Outreach and PR messages targeting the farm community, allied organizations, the general public, and political leaders regarding the safety of glyphosate-based herbicides.

98. Engaging independent scientists in research, outreach, and PR activities is routine across the pesticide industry. But in my opinion, the degree to which Monsanto shaped and controlled the activities and communications of "independent" scientists is unprecedented.

99. My review of the discovery record leads me to conclude unequivocally that the actions and activities of Monsanto's Third Party Network of scientists were not focused on deepening scientific understanding of Roundup risks, nor on finding the best ways to avoid possibly high-risk applications. The Network was managed and deployed to reinforce Monsanto talking points and science judgements, particularly those that were out of step with science published in peer-reviewed journals or the views of Monsanto consultants, like Dr. Parry.

100. The more formal statement of the "Overall purpose" of Monsanto's "Glyphosate Scientific Outreach Plan" (SO Plan) appears at the beginning of a June 1999 document:

> "Ensure that Monsanto's glyphosate-containing herbicides are widely viewed throughout the scientific community as posing no threat to human health or the environment. This support [from Third Party Network experts] will be used to favorably influence current and future possible challenges in the regulatory and public arena." (GLYMON00904774)

101. Note in particular the unconditional statement in the above-quoted paragraph -- "…no threat to human health of the environment." This statement stands in sharp contrast to more nuanced statements by scientists commissioned by Monsanto to review the genotoxicity or oncogenicity literature, or by the EPA. For example, the abstract of Kier and Kirkland's 2013 review of glyphosate genotoxicity ends with this statement:

> "Glyphosate and typical GBFs [GBHs] do not appear to present significant genotoxic risk under normal conditions of human or environmental exposures."

102. Based on the contents of this 2013 review, I conclude that Kier and Kirkland do not rule out the possibility of ***some*** genotoxic risk from exposures to GBHs under normal conditions, nor the possibility of ***significant*** genotoxic risk in the event of unusually high GBH exposure episodes. In my opinion, both such possibilities are generally consistent with the results of the 2016 EPA review, as well as the IARC review.

**2. Cherry Picking Science**

103. The record in this case shows, in my opinion, that Monsanto does not, in general, use science in the organized pursuit of knowledge and deeper understanding of the potential human and environmental risks stemming from applications of Roundup herbicides, but rather to gain new product registrations, and defend the company's Freedom to Operate, especially when jeopardized by new information regarding potential risks.

104. In many instances discussed in this report, Monsanto has selectively drawn upon the results of studies, cherry-picking the findings most favorable to its position and desired outcome, while ignoring, or criticizing those findings that caste a less favorable light on the safety of glyphosate and Roundup herbicides.

105. Based on my review of the record, Monsanto's biased and selective use of science is systemic and recurrent, and is driven predominately by the corporate goal of protecting glyphosate's Freedom to Operate.

106. In my opinion, in every aspect of its "Scientific Outreach" program, in communications with regulators, public presentations and commentaries, and via ghost-written materials, Monsanto spins science to support its FTO and attain the company's regulatory objectives.

107. I further conclude that Monsanto rarely uses science as a structured path to deeper insights on the properties and toxicity of its products, so that better ways can be identified to manufacture inherently safer Roundup-brand herbicides, and then also assure they are applied as safely as possible.

## III. Expert Background and Qualifications

109. I received a B.A. in Economics from Harvard University in 1971, and a Ph.D. in Agricultural Economics from the University of Wisconsin in 1980. I have worked on the impact of agricultural technology on pesticide use, efficacy, and risks, as well as on public health and farmer costs for nearly 40 years.

110. My work has encompassed the impacts of regulatory policies, requirements, actions, and laws on pesticide use, dietary exposure, worker risks, pest management systems, and food quality and safety.

111. I was the Staff Director of the Subcommittee on Department Operations, Research, and Foreign Agriculture ("DORFA") of the House Committee on Agriculture for three years (1981 to 1983). This Subcommittee had jurisdiction over the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), the primary federal statute governing pesticide regulation.

112. During this period, I organized several DORFA hearings on pesticide issues, and worked with Members of Congress in drafting potential changes in federal laws impacting the Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP). During my tenure as the DORFA Staff Director, around one-half of the time and focus of the Subcommittee was devoted to pesticide regulatory issues.

113. I made dozens of visits to OPP headquarters during this time-period, collecting information and speaking with OPP management, staff, and scientists on issues that had been brought to the attention of the Subcommittee, as well as issues of concern to OPP. These visits resulted in the flow of substantial information from OPP to the Subcommittee. Information provided by OPP helped the Subcommittee prioritize the issues addressed in forthcoming

Subcommittee hearings, and/or in need of legislative intervention.

114. On behalf of the Subcommittee, I organized several hearings on pesticide regulatory activities, issues, and controversies. This entailed drafting a hearing charter (purpose, focus, goals), identifying and securing the participation of witnesses, managing the flow of information submitted as part of delivered testimony, and preparing the hearing report issued by the House Committee on Agriculture.

115. The Subcommittee carried out a two-year investigation of pesticide regulatory policy and issues, with a principle focus on OPP/EPA activities. Several controversial areas of EPA action, or inaction, arose during the investigation. These included the OPP and industry response to the IBT scandal, the role of state versus federal government agencies in pesticide regulation, the way known or possible carcinogenic pesticides were regulated, the timeliness of OPP decision-making, the burden of proof governing OPP suspension and cancellation actions, the cost of program activities and possible need for user fees, state versus federal roles, among other issues.

116. During the DORFA investigation of OPP activities, I visited OPP in Crystal City multiple times. I met with managers in the various divisions of OPP, as well as with staff scientists in the residue chemistry, toxicology, and registration divisions. I interacted with most of the senior OPP administrators and staff who were responsible at the time for OPP's assessment and regulation of glyphosate herbicides.

117. The DORFA Subcommittee investigation culminated in the publication of a Subcommittee report (Volume I), and three supporting volumes of information (Volumes II-IV).

118. The IBT toxicological data scandal was among the issues explored in the Subcommittee's investigative report and supporting volumes. At the request of the

Subcommittee, OPP provided a detailed accounting of the pesticide-company studies submitted to OPP from IBT. The list included several studies commissioned by Monsanto on glyphosate. In fact, most of the initial data supporting the first regulatory decisions on glyphosate in the 1973-1980 period was from IBT, and was subsequently deemed invalid and/or fraudulent. All such studies had to be replicated, and were replicated during the 1980s and 1990s.

119. While serving as the DORFA Subcommittee Staff Director, I met multiple times with Mr. Chester Dickerson. Mr. Dickerson worked for Monsanto and was based in the corporation's Washington, D.C. office. Mr. Dickerson attended nearly all pesticide-related hearings conducted by the Subcommittee in the time period I worked as Staff Director.

120. Mr. Dickerson advanced his, and Monsanto's views regarding the way the OPP was implementing federal pesticide law. We discussed many times the OPP response to the IBT scandal, and the subsequent steps Monsanto took to replace fraudulent data. Other common topics of discussion included the need for legislative reforms, pesticide risk-assessment issues, and how known or possible oncogenic pesticides were being regulated.

121. From 1984-1990 I served as the Executive Director of the Board on Agriculture, a major unit of the National Academy of Sciences/National Research Council ("NAS/NRC").

122. In February 1985, the EPA "asked the Board on Agriculture ("BA") of the National Research Council to study the EPA's methods for setting tolerances for pesticide residues in food. Specifically, the EPA asked the board to examine the current and likely future impacts of the Delaney Clause on the tolerance-setting process" (quote from preface, *Regulating Pesticides in Food: The Delaney Paradox*, NAS, 1987).

123. My job was to support the BA's work in recruiting the study committee, collecting necessary information and records from the OPP, commissioning and overseeing

analytical work in support of the Committee's deliberations, and drafting the Committee's report, which was entitled *Regulating Pesticides in Food: The Delaney Paradox*.

124. The report was released in 1987. It estimated the level and distribution of potential cancer risk across foods, stemming from the about 2,500 tolerances covering the residues in food of 53 oncogenic pesticides. It also called for the reform of the Delaney Clause's paradoxical impact on pesticide tolerance setting.

125. In 1988, the Congress directed the EPA to request the Board on Agriculture of the NAS/NRC to conduct a study on the unique vulnerability of pregnant women, infants, and children following pesticide exposures. This new study was commissioned as a follow-up to the *Delaney Paradox* report.

126. As ED of the Board on Agriculture, I developed the scope of work, helped the Board identify and recruit the study committee, and supported the initial 2.5 years of the Committee's work. I left my position as the ED of the Board on Agriculture in late 1990.

127. The report written by the new NAS/NRC Committee was entitled *Pesticides in the Diets of Infants and Children*. It was released in June, 1993. Hearings on the report were held in both the House and Senate on the day of release. The recommendations were widely embraced by the pesticide industry and environmental/consumer advocates, and providing the basic framework for an historic piece of legislation that was passed and signed into law in the summer of 1996, the "Food Quality Protection Act" ("FQPA").

128. I started Benbrook Consulting Services ("BCS") in late 1990. Since that time BCS has carried out dozens projects involving pesticide use, risks, and regulation for federal and State government agencies, companies, private institutions, and non-governmental organizations.

129. In the 1990s, several BCS projects involved analytical work on risks stemming

from residues of cancer-causing pesticides in food. The impact of the Delaney Clause, and possible legislative changes to it, was a focus of all such projects, as was the long-standing effort by the Congress to pass legislation implementing the recommendations in the 1987 and 1993 NAS/NRC reports.

130. BCS's major client in the 1993-2002 period was Consumers Union ("CU"), publisher of Consumer Reports. I was hired initially to work with senior CU scientific staff in writing a book on pest management, and pesticide use and regulatory issues in the U.S. *Pest Management at the Crossroads* (*PMAC*) came out in October 1996 and was widely disseminated in pesticide policy circles.

131. Chapter 3 in *PMAC* addressed human-health risks stemming from pesticide use and exposure, and notes that "More than 70 active ingredients cause cancer in animal tests, and cancer has been the most common reason cited by the EPA in pesticide cancellation and suspension actions."

132. Chapter 4 in *PMAC* focuses on pesticide regulation and includes a detailed explanation of the purpose, provisions, and impact of the 1996 Food Quality Protection Act, with multiple references to both the 1987 and 1993 NAS/NRC reports.

133. The FQPA changed the basic standard and risk-assessment process governing the setting of tolerances in the case of possibly cancer-causing pesticides that are known to concentrate in processed foods.

134. The FQPA's core reforms were effective upon enactment, and required the EPA to revisit the 8,066 tolerances covering residues of pesticides then on the market. These included 130 tolerances covering all forms of glyphosate and its metabolites, as well as 14 additional tolerances covering residues of the isopropylamine salt form of glyphosate (the primary form of

glyphosate sold by Monsanto).

135. From late-1996 through about 2002 I continued work with CU on the implementation of the FQPA. I carried out multiple analytical projects for CU, the results of which were typically included in CU's rule-making comments to the EPA on various aspects of FQPA implementation. BCS also worked on FQPA implementation issues for other clients.

136. In 1996, the first genetically-engineered ("GE"), herbicide-resistant ("HR") soybean and cotton seeds were commercially sold. These crops had been engineered to tolerate post-emergent applications of glyphosate (i.e., an application over-the-top of a growing crop), and were labeled "Roundup Ready" crops. Applied in this way, at this stage of crop growth, glyphosate killed actively growing weeds in farm fields, but left GE crops unharmed.

137. The commercialization of GE-HR crops triggered rapid growth in the overall sales and pounds applied of glyphosate in the U.S., and globally.

138. I began Ag Biotech InfoNet in 1998, a website covering the use, risks, and regulation of genetically engineered crops. Herbicide-resistant crops, and especially Roundup Ready crops, were a major focus of the website, as was the use and regulation of glyphosate-based herbicides. The website was taken off the Internet around 2005 because BCS could no longer support the rapidly growing workload and expense required to keep it current.

139. As part of my ongoing analytical work since the early 1990s, I download the pesticide use data collected and released annually by the U.S. Department of Agriculture (USDA). Each year I track changes in herbicide use, as well as overall pesticide use in the three major GE crops – soybeans, corn, and cotton.

140. It was clear to me by the early 2000s that both herbicide and overall pesticide use was rising on acres planted to GE-HR soybeans, corn, and cotton, and that Monsanto claims that

its new, GE crops were reducing pesticide use were not supported by official USDA pesticide use data.

141. In 2003 I released the first of several reports on the impacts of GE crops on pesticide use. Ag BioTech InfoNet Technical Paper #6 was issued in 2003. It documented the increase in overall pesticide use on GE soybeans, corn, and cotton from 1996 through 2002. In 2004, Ag BioTech InfoNet released Technical Paper # 7, quantifying the impact of GE crops on pesticide use over the first nine years of use.

142. During my tenure as Chief Scientist of The Organic Center (TOC), I wrote and issued a November 2009 "Critical Issue Report" covering the impact of GE crops on pesticide use over the first 13 years of use. And in October 2012, I published a paper entitled "Impacts of genetically engineered crops on pesticide use in the U.S. – the first 16 years" in the peer-reviewed journal *Environmental Sciences Europe*.

143. Each of the reports I wrote on the impact of GE crops on overall pesticide use highlighted the role of rapidly-rising use of glyphosate-based herbicides in pushing upward the overall pounds of pesticides applied by U.S. soybean, corn, and cotton farmers.

144. The reason why was clear and not in dispute – farmers who planted Roundup Ready crops switched away from herbicides generally applied at a rate of 0.01 pound of active ingredient per acre to over 1.0 pounds, and averaging about 0.3 pounds per acre. Glyphosate-based herbicides, on the other hand, were typically applied at an average rate per crop year of between 1 and 2 pounds of glyphosate per acre. Replacing two herbicides applied at 0.3 pounds per acre, with one application of glyphosate at 1.0 pound per acre increases herbicide use, when "use" is measured by average pounds of active ingredient applied per acre (the most common metric used by EPA and the USDA).

145. In 2016, I published the first complete accounting of the use of glyphosate-based herbicides in the U.S. and globally, based on publicly available pesticide use data. The paper was entitled "Trends in glyphosate herbicide use in the United States and Globally" and was published in *Environmental Sciences Europe* (Vol 28:3; DOI 10.1186/s12302-016-0070-0).

146. Also in 2016, I was the principle and senior author of a paper entitled "Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement" that was published in the peer-reviewed journal *Environmental Health* (Volume 15:19; DOI 10.1186/s12940-016-0117-0).

147. From late 1990 through 2006, I ran BCS and all my work was via contracts with BCS.

148. From 2006 through mid-2012, I worked as the Chief Scientist of The Organic Center, a small non-profit responsible for tracking new science on the environmental and consumer health impacts of organic food and farming. The impact of organic farming on pesticide use and risks was an ongoing focus during my tenure as TOC Chief Scientist.

149. I received a non-tenure track, Research Professor appointment at Washington State University in June 2012, a position I held for three years. During this time, I ran the "Measure to Manage" program. Our focus was development and application of analytical tools useful in quantifying the impact of agricultural technology and farm production systems on agriculture's environmental footprint and public health outcomes.

150. As a result of research collaborations with Newcastle University scientists, I was appointed as a Visiting Professor in the School of Agriculture, Food and Rural Development, Newcastle University in the United Kingdom.

151. In March 2017, I became a Visiting Scholar in the Department of Environmental

Health and Engineering in the Bloomberg School of Public Health, Johns Hopkins University.

152. Both of these academic appointments are ongoing.

153. In the last four years, I have been deposed in the following cases:

- Laura Eggnatz, Katrina Garcia, and Julie Martin v. Kashi Company. Civil Case No.: 12-21678-CIV-Lenardo/O'Sullivan, U.S. District Court, Southern District of Florida, Miami Division.

- Barron v. Snyder's-Lance, Inc. No. 0:13-cv-62496-Leonard-Goodman (S.D. Fla.).

- In re General Mills, Inc. Kix Cereal Litigation, Case No. 12-249 (KM) (JBC),U.S. District Court of New Jersey

- Monsanto litigation on non-Hodgkin lymphoma: Two-day deposition in the Dewayne Johnson v. Monsanto Company, Case No. CGC-16-550128, Superior Court State of California County of San Francisco; two depositions in the Hall-Peterson case; one deposition in the Adams case; and trial testimony in the Johnson case in the Superior Court of the State of California.

154. I charge $300.00 per hour for my expert witness work and travel. My professional fee for time in depositions is set on a case by case basis.

155. My resume appears in Appendix A and includes my litigation history.

## IV. The EPA Pesticide Regulatory Decision Process

156. The data requirements, risk assessment protocols, and decision criteria supporting pesticide regulatory decisions made by the OPP/EPA change incrementally over time. The changes have, to varying degrees, tracked scientific advances in the underlying residue chemistry, toxicology, and environmental sciences.

157. Sorting out the impact of changes over time in data requirements, study protocols, risk assessment methods, decision criteria governing OPP regulatory actions, and politics is a complex endeavor, especially in the case of a pesticide like glyphosate that has been registered by EPA since the mid-1970s and gone through such profound changes in use, test results, levels and patterns of exposure, and risk assessments.

158. Changes in when, where, how, and how widely a pesticide is used often occur over time, and such changes typically alter exposure and risk levels in ways that are hard to predict. In my opinion, the record in this case shows clearly that this is indeed the case with glyphosate and GBHs.

### A. Three Major OPP/EPA Actions and Decisions

159. There are three major types of pesticide regulatory actions and/or decisions made by the OPP: (1) a "yes"/"no" response, or a conditional or amended "yes," to a petition from a pesticide manufacturer asking the EPA to establish new tolerance(s) covering residues of a pesticide in food(s) derived from a crop or crops for which the pesticide will be labeled for use; (2) a "yes"/"no" response, or an amended or conditional "yes," to an application from a pesticide manufacturer for a registration (i.e., label) newly authorizing a pesticide product for use on specified crops under defined conditions; and (3) a cancellation, suspension, or refusal to re-register an existing registration for a pesticide already on the market; or, re-registration of an

existing product under different, and usually restricted terms and conditions.

160. Each of these three types of decisions and actions arises from well-defined OPP regulations that set out application, review, risk assessment, and approval/denial processes. These processes typically require companies to conduct new studies, and submit new data to the agency to "support" any requested, new tolerances or registered uses.

161. Once all, or most of the requested and/or required information is submitted to OPP, a scientific review is undertaken of submitted studies in the residue chemistry, toxicology, or environmental effects branches.

162. OPP staff determine whether: (1) all required studies have been undertaken and submitted, (2) the studies were conducted in accord with Good Laboratory Practices (GLP) and other requirements set forth in EPA guidance and policy documents, and (3) study results support the "gateway" OPP action(s) or decision(s) requested by the applicant/registrant.

163. By "gateway actions," I mean actions or decisions that OPP/EPA must make prior to approving a new registration application. The three most important are:

a. The setting of a tolerance level at "x" parts per million in food "y." Tolerances are set at the level needed to cover residues of the pesticide likely to be in crop "y" at harvest after an application made in accord with all label directions, or in foods made from crop "y".

b. Establishing a mammalian chronic Reference Dose at "z" milligrams of pesticide per kilogram of bodyweight. A chronic Reference Dose (cRfD) is the key human-exposure benchmark that cannot be exceeded by approved registrations of a pesticide. It is measured in milligrams of pesticide active ingredient per kilogram of an individual's bodyweight, per

day.

c. Whether the pesticide has potential to cause cancer. Pesticides are classified by OPP/EPA as a possible, probable, or proven oncogene, or not carcinogenic, or unknown as to oncogenic potential.

**B. Applications to Register a New Pesticide**

164. In the case of an application for a food crop use, or uses, of a new pesticide active ingredient, the OPP must decide which data requirements must be satisfied prior to making a final "yes"/"no" decision. Required and submitted studies must be evaluated by OPP for adherence to study protocols and Good Laboratory Practices (GLPs) set forth in OPP's data requirements in Section 408 of the Code of Federal Regulations.

165. Any required tolerances must be approved and in place prior to final OPP action in response to a registration application.

166. Companies generate studies and collect substantial data to submit to the OPP in support of requested actions. Initial tolerance petitions are typically accompanied by the toxicology studies conducted by the petitioner, as well as request for EPA to establish the pesticide's chronic Reference Dose at a given level, expressed as milligrams of pesticide per kilogram of bodyweight per day. A pesticide's chronic Reference Dose (cRfD) establishes the maximum amount of the pesticide that a person of known weight can be exposed to in a day, without exceeding the EPA's "level of concern".

167. In the event estimated exposures exceed the EPA's "level of concern," the agency will either request additional data to refine its estimates of exposure and risk, or impose restrictions on labeled uses that bring expected exposures below the agency's "level of concern".

168. Once all requested data is submitted and deemed acceptable (i.e., it satisfies OPP-

imposed data and GLP requirements), OPP science-branch managers then determine whether submitted studies support the actions requested by applicants (set a tolerance, register a new use of a pesticide). The key decision criterion is whether the exposure levels likely to occur following use of a pesticide in accord with its label directions might exceed EPA's "level of concern."

169. Such "levels of concern" vary depending on: (1) the exposed organism; (2) the vulnerability of population groups; (3) the type of risk under review (e.g., acute, chronic, reproductive); (4) whether individuals are exposed to average levels of chronic exposure expected across the U.S. population, or are exposed as a result of occupational use of a pesticide, and (5) the magnitude, persistence, and reversibility of any possible adverse effects.

170. The level of certainty/uncertainty in OPP exposure or risk assessments also plays a role in determining whether the agency's "level of concern" has been exceeded.

171. The EPA will approve the registration of a new pesticide if all applicable data requirements are satisfied, and no estimated exposure levels for non-target organisms (e.g., people, birds, bees, fish), exceed EPA's "level of concern."

172. In some cases, the OPP will grant a "conditional registration" for a new pesticide, or a new use of a previously registered pesticide. Such registrations are accompanied by a requirement that the registrant must conduct and submit additional studies or data to OPP by a given date.

### C. Actions Impacting the Future Use of an Already-Registered Pesticide

173. In the case of re-registration, cancellation, and suspension actions impacting already-registered pesticide uses, the EPA is bound by the FIFRA statute to balance the risks and benefits associated with ongoing or altered use of the already-registered pesticide.

174. As stated in the 1996 Consumers Union book *Pest Management at the Crossroads*, "new pesticides are guilty until proven innocent, with applicants bearing the burden of proof. Old pesticides are innocent until proven guilty, with EPA bearing the burden of proof" (page 93).

175. Before restricting the use of a previously registered pesticide, OPP must first show that: (1) exposure levels to one or more non-target organisms (and especially people), exceed the EPA's level of concern, and (2) the risks stemming from the ongoing use of the pesticide exceed the benefits flowing from such uses.

176. To make judgements regarding risks versus benefits, the OPP must carry out detailed assessments of how a given pesticide is used on a given crop, pesticide efficacy (number and severity of pests controlled, how well are they controlled, and for how long), how use varies across the country, the cost of the pesticide plus its application, and what combination of factors can lead to exposures above EPA's level of concern.

177. This use-specific information is used by the EPA to identify relatively high-risk uses, as well as options to reduce exposure levels. At the end of its assessment of pesticide uses, benefits, and risks, the OPP must decide whether restricting or cancelling the use of a pesticide will cause unacceptable crop losses or damage, and/or force farmers to increase reliance on another pesticide that might pose even more serious risks.

**D. Impacts of OPP Cancer Determinations on Tolerance Setting**

178. An "oncogen" is a chemical thought to possibly increase the risk of triggering growth of benign and/or malignant tumors. A "carcinogen" is a substance thought to trigger the growth of malignant tumors. Oncogenicity is the capacity to cause or amplify growth of benign or malignant tumors, while carcinogenicity is the capacity to trigger or amplify growth of

cancerous, malignant tumors.

179. The EPA was formed in 1972. According to a 1994 EPA document, cancer risk had been, at that point in the agency's history, the most commonly cited reason for OPP pesticide cancellation and suspension actions (*Status of Pesticides in Reregistration and Special Review*, 738-R-94-008).

180. As of the mid-1980s, the NAS/NRC report *Regulating Pesticides in Food – The Delaney Paradox* identified about 2,500 tolerances covering residues of 53 food-use pesticides thought by EPA to pose some level of cancer risk (NAS/NRC, 1987).

181. As of June 1986, there were 8,477 food tolerances in the Code of Federal regulations, so about 30% of all tolerances covered uses of possibly oncogenic pesticides (data on number of tolerances from Table 2-1, p. 35, NAS/NRC, 1987).

182. Congressional hearings conducted by the DORFA Subcommittee in 1981-1983 included testimony from OPP officials, the pesticide industry, and consumer health advocates on OPP methods and policies governing the regulation of possibly cancer-causing pesticides.

183. Special focus was directed to the conundrum faced by OPP/EPA in working through sometimes conflicting statutory standards applicable to the tolerance setting process in the case of certain possibly oncogenic pesticides. The "Delaney Paradox" arises from the conflicting mandates in the two statutes governing the tolerance setting process.

184. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is the dominant statute governing pesticide regulation. It directs the OPP/EPA to apply a risk/benefit balancing standard in deciding whether to approve a pesticide registration, reregister an already-approved pesticide use, or cancel or suspend an existing registration.

185. According to the OPP –

> "Before EPA may register a pesticide under FIFRA, the applicant must show, among other things, that using the pesticide according to specifications 'will not generally cause unreasonable adverse effects on the environment.' FIFRA defines the term 'unreasonable adverse effects on the environment' to mean: '(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act.'"
>
> *Summary of the Federal Insecticide, Fungicide, and Rodenticide Act*, https://www.epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act)

186. A second federal statute establishes the authority for OPP/EPA to set tolerances -- the Food, Drug, and Cosmetic Act ("FDCA"). Section 408 was added to the FDCA in 1954 to provide a mechanism for the Food and Drug Administration (FDA) to control pesticide residue levels in food.

187. Section 408 authorizes the establishment of tolerances in raw agricultural products at the point they would typically leave the farm gate. Section 408 requires such tolerances be set at levels deemed necessary to protect public health. Residues in excess of the applicable tolerance renders food adulterated and, hence, unlawful for sale.

188. Responsibility for establishing tolerances under Section 408 was granted to the EPA upon formation of the agency in 1972.

189. Section 409 of the FDCA provides the FDA general authority to regulate food additives – "any substance the intended use of which results or may reasonably be expected to result…in its becoming a component of the food." 21 USC § 321(s) [1984].

190. Section 409 goes on to exempt pesticide residues in food up to the level authorized by a Section 408 tolerance applicable to the given food, recognizing that such levels are subject to control via the tolerance setting process.

191. However, in some cases, pesticide residues in raw agricultural commodities concentrate in processed agricultural products, or food ingredients derived from the raw agricultural commodities. Common examples include residues in raisins, in contrast to the grapes the raisins come from (and indeed any dried food); milling wheat to produce wheat germ and flour; making tomato paste or ketchup from raw tomatoes; or, extracting oils from crops like canola, soybeans, or olives.

192. As in the case with Section 408, EPA has been granted the responsibility of setting tolerances under the authority granted in Section 409 of the FDCA.

193. In 1958, Congress amended Section 409 of the FDCA to include the so-called Delaney Clause (named after its author, New York congressman James Delaney). The clause states that ”the Secretary of the Food and Drug Administration shall not approve for use in food any chemical additive found to induce cancer in man, or, after tests, found to induce cancer in animals.”

194. The Delaney Clause applies to all food additives regulated under Section 409 of the FDCA, including pesticide residues in processed foods that concentrate above the level in the corresponding raw agricultural commodity.

195. Based on the EPA’s interpretation of the requirements in Section 409, the key factor in determining whether a Section 409 tolerance can be granted is whether a pesticide residue concentrates in a processed food above the level typically found in the raw agricultural commodity, not whether the level in the processed food is expected to exceed the Section 408 tolerance level.

196. In the 1980s and 1990s, EPA denied the registration of several new pesticides and/or new uses of an already-registered pesticide that OPP had classified as a possible or

probable oncogen, because a Section 409 food-additive tolerance was required.

197. Glyphosate was among the pesticide active ingredients that was directly impacted by the Delaney Clause from 1983 into the 1990s, by virtue of OPP's classification of glyphosate as a possible human carcinogen in 1983.

## V. Early EPA Actions on Glyphosate Herbicide

198. The Office of Pesticide Programs (OPP) in EPA processed the initial tolerance petitions and registration applications for Monsanto's new herbicide, glyphosate, in the 1974-1977 period, just after the formation of the EPA in 1972.

199. Glyphosate is a broad-spectrum herbicide that kills any growing plant, tree, vine, or shrub, whether regarded as a weed or a crop. The herbicide is most effective when sprayed on young and immature plants; higher doses are required to kill well established, more mature plants, vines, and trees.

200. Because of the indiscriminate nature of glyphosate, the herbicide cannot be sprayed on any crops, trees, vines, or other desirable vegetation after the plants have germinated and are actively growing. However, glyphosate is sometimes sprayed on crop fields prior to harvest to kill the mother plants, to accelerate harvest operations. Such desiccation applications of a GBH required the setting of much higher tolerances in the 1990s and 2000s for certain crops and foods.

### A. Initial Uses and Tolerance Actions

201. The first EPA actions on glyphosate occurred in 1974 and entailed approval of temporary tolerances for the combined residues of glyphosate and its metabolite aminomethylphosphonic acid (AMPA) in the crops harvested from 9,715 acres of experimental crop uses of glyphosate. The temporary tolerances requested were: corn fodder and foliage at 0.5 ppm; cottonseed and cotton forage and hay at 0.5 ppm; and corn, soybean, and wheat grain at 0.1 ppm.

202. These temporary tolerances, along with similar tolerances on several other crops, were approved and eventually became permanent tolerances, in response to tolerance petitions

4G1444, 5G1523, 5G1561, and 5F1560.

203. The first agronomic crops on which glyphosate herbicides were registered for use were cotton and soybeans. On March 5, 1976 Monsanto requested EPA to establish temporary tolerances on cottonseed and cotton forage, and soybean grain, hay, and forage, in order to allow harvest and use of crops grown under an Experimental Use Permit. (MONGLY03579293).

204. EPA approved Monsanto's request for temporary cotton and soybean tolerances in a letter dated September 7, 1976. The tolerances would be in effect for one year.

205. The letter goes on to alert Monsanto that: "A food additive tolerance is being established for residues of glyphosate and its metabolite in soybean hulls at 20 ppm." So, from September 1976, Monsanto would have to request, and EPA approve, Section 409 (FDCA) food additive tolerances for most new glyphosate food crop uses.

206. Such tolerances were then subject to the Delaney Clause and would not be approved by EPA in the event glyphosate was determined to be a possible, probable, or proven animal or human oncogen.

207. Over the next 10+ years, several other applications for Experimental Use Permits ("EUPs") were submitted and most were granted by EPA, sometimes in a modified form. In addition, most of the requests for temporary tolerances required to allow crop harvest following Roundup applications authorized by EUPs were approved. But most of these approval letters from EPA to Monsanto contained a paragraph explaining that the agency had also established necessary Section 409 food additive tolerances, on a temporary basis.

208. Both the number and scope of pending temporary and permanent tolerance petitions expanded steadily during the late 1970s, as did the number of tolerances that were granted.

209. The status of OPP actions on 21 pending glyphosate tolerance petitions is discussed in a March 15, 1977 Toxicology Branch memo by Raymond Landolt. It identifies the data supporting existing tolerances, the need for some additional studies, and corrects an error in an earlier memo regarding the no effect level in a three-generation rat reproduction study.

210. It also includes the following passage: "TB [Toxicology Branch] memo of June 4, 1974 concluded that 'the residue on human food crop are negligible and the fraction that is non-extractable would be sufficiently low to be toxicologically insignificant.'"

211. In 1975, permanent tolerances covering the combined residues of glyphosate and AMPA were established at 0.1 ppm for corn and soybean forages and grain, as well as for wheat, sorghum, oats, and barley grain and forages. With the exception of soybean, corn, and the wheat straw tolerances, the above tolerances remained in place at the 0.1 ppm until 1996.

212. Wheat, soybean, and corn tolerances were increased 10- to 2,000-fold between 1980 and 2011:

a. Wheat grain from 0.1 ppm in 1990 to 5 ppm in 1996, and then to 30 ppm in 2008. Wheat straw from 0.1 ppm to 40 ppm in 1990, and then to 85 ppm in 1996 and 100 ppm in 2000;

b. Soybean grain from 0.1 ppm to 6.0 ppm in 1985, and then up to 15 ppm in 1990, and to 20 ppm in 1996, while the soybean hay tolerance rose from 0.1 ppm to 200 ppm in 1990; and

c. Corn grain and forage tolerances rose from 0.1 in 1990 to 1.0 ppm in 1997. Corn field forge rose again to 6 ppm in 2003. The corn grain tolerance was increased in 2011 to 13 ppm. Corn stover (cobs, leaf and stalk residue that remain in fields) tolerance rose from 0.1 ppm to 100 ppm

in 1997.

213. These tolerance increases were needed for two reasons. First, in the case of corn and soybeans, to cover the much higher residues stemming from emerging and new uses of Roundup herbicide in conjunction with crops genetically engineered to tolerate post-emergent, or "over-the-top" applications of Roundup.

214. Second, on February 21, 1986, Monsanto submitted an application to OPP seeking registration of preharvest use of glyphosate on soybeans. Such uses were intended to kill the growing plants to accelerate harvest and/or preparation of treated fields for the planting of another crop. (MONGLY03692349). The application included a list of proposed changes in soybean tolerances required to cover residues in soybean grain and hay. In addition, Monsanto acknowledged that a Section 409 food additive tolerance in soybean hulls would be required and proposed that it be set at 100 ppm.

215. But as long as EPA considered glyphosate a possible oncogen, approval of the Section 409 tolerance in soybean hulls would likely not occur. For example, in an April 18, 1985 memo to the Registration Division and Toxicology Branch from the Residue Chemistry Branch, R.W. Cook reviews a pending tolerance petition that requests increases in glyphosate plus AMPA tolerances in wheat grain and wheat straw. The memo states: "4b. TOX has concluded (W. Dykstra, 3/19/85) that food additive tolerances for glyphosate are not appropriate due to the Delaney rule." (page 4) (MONGLY00221717).

**B. Studies on Glyphosate Conducted by Industrial BioTest**

216. Early interactions between OPP and Monsanto were complicated by the Industrial BioTest ("IBT") pesticide data scandal.

217. IBT was a contract laboratory doing toxicological studies destined for submission

to OPP for many pesticide manufacturers in the 1970s and 1980s.

218. In 1976, a routine FDA audit of an IBT test facility uncovered problems with the conduct of some studies and lead to a thorough EPA assessment of all studies done by IBT that supported regulatory actions by OPP.

219. Most of the initial toxicological database supporting the early tolerance petitions and registrations of glyphosate were done by IBT. The "IBT Tracking System Report" released in 1983 notes 30 studies done by IBT on glyphosate, of which 17 were invalid and 2 were pending final judgements (Exhibit B, "Summary of the IBT Review Program," OPP, July 1983). These invalid studies included long-term carcinogenicity rodent studies.

220. On July 1, 1977, OPP generated a one-page summary of the eight toxicology studies used to support establishment of ***all*** existing glyphosate tolerances. These eight studies were submitted between 1972 and 1974, and all were done by IBT.

221. An August 21, 1978 memo from William Dykstra of the Toxicology Branch to Robert Taylor in the Registration Branch discusses the EPA's assessment of the validity of a key, 2-year chronic toxicity study done in Albino rats by IBT. For a variety of reasons, the EPA judged the study to be invalid, yet it served as the basis of the then-current chronic Reference Dose of 0.1 mg/kg/day (called an ADI, or Acceptable Daily Intake in 1978).

222. A July 27, 1982 memo from the Toxicology Division to the Registration Division reported EPA's judgement that the 2-year dog study (No. 651-00565) done by IBT for Monsanto and completed in 1973 was invalid because of missing data, failure to record diet preparation records, and other deficiencies.

223. Accordingly, it took about a decade for EPA to determine that most of the toxicological database submitted to the agency by Monsanto in the mid-1970s, and used by EPA

to support all early EUP, tolerance, and registration actions, was invalid.

224. Problems also arose with some of the replacement studies that Monsanto commissioned to replace invalid IBT studies. In July 1979, Monsanto decided to terminate a 2-year mouse study on NNG (a glyphosate breakdown product) because of excessive mortality in treated groups of animals. (MONGLY04272266).

225. Via an agreement with OPP, Monsanto repeated all the invalid IBT studies at different laboratories, mostly during the 1980s. In the interim, EPA allowed existing registrations and tolerances to remain in place. Accordingly, for about a decade, the early registrations and tolerances covering all uses of glyphosate were not supported by a set of valid toxicology studies.

### C. Contaminants, Adjuvants, and Surfactants

226. The EPA grants two basic types of registrations and labels for pesticides: technical use registrations and labels; and, formulated, "end use" product registrations and labels.

227. A first step in the regulatory process typically entails a chemical company applying for and gaining a technical use product label covering a product composed of 100%, or nearly 100% pure active ingredient. Such registrations are typically granted to basic manufacturers that are involved in pesticide discovery research and development, and own and/or operate chemical plants synthesizing pure, 100% pesticide active ingredients.

228. EPA-approved labels issued for technical use products generally do not include detailed lists of approved crop or industrial uses, rates of application, or other specific use instructions. They do address proper handling, storage, and transport methods and precautions.

229. Technical use pesticides may be used internally by the manufacturer to make its own brand-name, formulated products, like Roundup.

230. Technical use products are also sometimes sold to other pesticide companies that formulate "end use" products labeled for specific uses. Such "end use" products are ready to be used and applied by farmers, applicators, home owners, land managers, or other people involved in pest management.

231. The distinctions between technical use and end-use products are important for many reasons. Different data requirements apply. End use products often have a substantially different set of environmental fate properties, compared to the pure active ingredient(s) in them. These differences can significantly alter the nature and outcome of both environmental and human-health risk assessments and outcomes.

232. Ounce for ounce, end-use products are usually less toxic to most organisms than pure active ingredients, but some important exceptions occur, including glyphosate and GBHs.

233. Companies seeking and obtaining end-use product labels are responsible for a much more extensive set of decisions regarding formulations, uses, rates, and methods of application, than companies just seeking and gaining technical use registrations.

234. In addition, end-use pesticide products contain much more extensive label directions and safety precautions that will hopefully assure that the pesticides do not cause any "unreasonable adverse effect on man or the environment."

235. The "label is the law" is a central provision in federal law that applies to all pesticide labels. The presumption is that when a pesticide is applied in accord with all label directions, there will be no "unreasonable" adverse impacts on people or the environment. If or when such adverse effects arise following legal, on-label application(s), the pesticide product is deemed "mislabeled" under FIFRA, regardless of EPA's role in crafting, reviewing, and approving existing label language.

### D. Sources of Pesticide Product Risk

236. Human health and environmental risks from pesticide use can arise from three general categories of ingredients, or components, in a commercial pesticide product: (1) the active ingredient itself, (2) any impurities in the active ingredient that are formed during the manufacturing process, or as a result of a chemical reaction that occurs between the time the pesticide is made and/or mixed at a plant and applied by a user, and (3) the so-called "inert ingredients" added to certain end-use products (e.g., surfactants and adjuvants).

237. "Inert ingredients" are added to liquid, end-use pesticide products like Roundup herbicide to assure that the active ingredient (glyphosate): (a) remains thoroughly mixed and stable, (b) is compatible with other pesticides or liquid fertilizers that might be combined in a tank-mix and applied via a single pass through a field, and (c) adheres to, and penetrates into whatever weeds or unwanted vegetation the herbicide is sprayed on.

238. Herbicide adjuvants and surfactants are regarded as "inert ingredients" by EPA because, in general, they do not contribute directly to the capacity of the herbicide to kill or control weeds. But several inert ingredients, by themselves, pose toxicological and/or environmental risks, and hence are not "inert" in the sense of contributing to the risk profile of an end-use herbicide product.

239. In addition, several herbicide surfactants, including most of those used in formulating Roundup-brand herbicides since the 1970s, alter the environmental fate and toxicological risk profile of GBHs, compared to glyphosate technical.

240. In the case of formulated Roundup, surfactants increase herbicide efficacy by enhancing the movement of the glyphosate in the formulated product through the surface of plant leaves, into the inside of the plant where it is protected from rainfall and sunlight.

### 1. Impurities in Glyphosate Active Ingredient

241. There are two impurities associated with Roundup herbicides that have received considerable attention over the years: NNG and formaldehyde. NNG is formed when glyphosate interacts chemically with nitrosating agents, to form the oncogenic nitrosamine contaminant NNG. The later contaminant is an unavoidable, low-level contaminant in glyphosate that occurs as a result of the manufacturing process used by Monsanto. (Wratten email of April 19, 2008 in MONGLY02530945; more detailed discussions of both NNG and formaldehyde in glyphosate appear in MONGLY03909609).

### 2. Adjuvants and Surfactants in Roundup End Use Products

242. The two major categories of inert ingredients are surfactants and adjuvants. Surfactants are added to formulated herbicides to "interfere with proper membrane function" (MONGLY01700591), such as keeping foreign chemicals, viruses, and bacteria out of cells.

243. Such differences can be important to regulators, applicators, and public health in cases where the inert ingredients in a pesticide alter the toxicity profile of the formulated pesticide product. This can happen in several different ways.

244. The primary surfactants used for years in Roundup formulations fall within the family of polyoxyethylene-alkylamine (POEA) surfactants. According to Monsanto, a POEA surfactant was generally present in a 3:1 ratio of glyphosate to POEA in the early years of commercial use, with the concentration of POEA falling to ratios around 7:1 in Roundup brands since ~2000. (MONGLY01700591).

245. Some inert ingredients change the properties of formulated pesticides, for example by increasing the persistence of a pesticide or its ability to penetrate cell walls, or both.

### 3. Heightened Toxicity Caused by the Surfactants in Formulated Roundup

246. The distinction between the risks associated with 100% pure active ingredients (i.e., glyphosate), in contrast to formulated products containing inert and active ingredients (i.e., Roundup or other GBH), is critical from the perspective of the accuracy of pesticide risk assessments.

247. Almost all of the testing required by the EPA has been on technical glyphosate, including all of the long-term animal oncogenicity tests. Hence, most EPA and Monsanto judgements and claims relative to the oncogenicity of Roundup, are based on tests conducted with pure glyphosate, an herbicide which no one has ever applied.

248. In the case of pure glyphosate versus formulated Roundup, the risks posed by the latter are greater than the former for two primary reasons: (1) the inert ingredients in Roundup (including their impurities) are more toxic than glyphosate itself, and (2) Roundup inert ingredients increase the amount of glyphosate reaching and penetrating cell walls in exposed mammals, and hence increase risk levels in exposed human populations.

249. A short paper in the medical journal *The Lancet* appeared in 1988 (Sawada, *et al.*, Probable toxicity of surface-active agent in commercial herbicide containing glyphosate, *The Lancet*, 1(8580): 299). The authors attributed acute, glyphosate-herbicide poisoning symptoms among several Japanese patients to the "inert ingredient" surfactant POEA in formulated Roundup, and not the active ingredient (glyphosate). The Japanese team reported that the acute lethal dose (i.e., LD-50) of POEA in animal studies is one-third that of glyphosate, which explains why the LD-50 of glyphosate active ingredient is higher (less toxic) than the LD-50 of Roundup herbicides formulated with the surfactant POEA.

250. This article in *The Lancet* triggered, to my knowledge, the first attention by independent scientists to the possible human health impacts of the inert ingredients in Roundup

herbicides. Among the adverse mammalian impacts of POEA noted by the Japanese scientists was damage to red blood cells.

251. Inert ingredients in formulated pesticide products can also, themselves, contain toxic impurities and contaminants. While pure glyphosate contains the nitrosamine-impurity NNG, the POEA surfactant in formulated Roundup products contains 1,4-dioxane.

252. A U.S. National Cancer Institute bioassay of 1,4-dioxane found that the chemical causes hepatocellular adenomas and carcinomas in the kidneys of rats ( https://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr080.pdf). In 1982, the International Agency for Research on Cancer classified 1,4-dioxane as a possible human carcinogen (IARC, IARC monographs on the evaluation of the carcinogenic risk of chemicals in humans. Supplement 4, WHO, 1982). An EPA report from 1986 listed 1,4-dioxane as a probable human carcinogen.

253. In July 1999, the Italian Pesticide Committee, a European regulatory body, held a meeting on the regulation of Roundup herbicide. It decided that new genotoxicity studies on both glyphosate and formulated Roundup would be required to assess genotoxicity and DNA reparation, following OECD Guideline 486 (1998). Such studies were needed to address risk issues arising from the interactions of impurities in pure glyphosate and the inert ingredients used to make formulated glyphosate-based herbicides, including Roundup.

254. Monsanto employee Gabrielle Fontana forwarded the news regarding this new genotoxicity study requirement to senior Monsanto scientists including Mark Martens, William Heydens, Donna Farmer, Larry Kier, and William Graham in a July 29, 1999 email. (MONGLY00877684).

255. In response, Martens said that the OECD 486 test “is not an unreasonable request but suggest some liver toxicity along with it to explain bumpy responses at the high dose. This

test has also been requested by the French for MON 4660 and there the risk is greater because of extreme liver toxicity." (MONGLY0877684).

256. A few hours later, William Heydens adds to the email chain: "I don't think an in vivo UDS [the OECD 486 test] is reasonable for glyphosate…Now, formulations are obviously another issue…liver toxicity with formulations could be a confounding factor, and we would have to design and conduct the study very carefully (using our alachlor & acetochlor experience) if we are ultimately forced to do it." (MONGLY00877684).

257. Two days later, Donna Farmer adds to this email chain, and writes: "Sorry I am weighing in on this late…It is too premature to discuss conducting any studies. I will not support any studies on glyphosate formulations or other surfactants at this time…". (MONGLY00877684).

258. Despite numerous studies published in peer-reviewed journals beginning in the late 1980s pointing to the heightened toxicity of Roundup formulations including POEA surfactants compared to pure glyphosate, Monsanto has to this day not conducted the studies needed to either confirm or refute concerns over differential toxicity. More importantly, to this day, Monsanto has never conducted a long-term animal carcinogenicity study on a GBH formulation or the POEA surfactant.

259. Some POEA surfactants have been restricted in Europe, based on safety concerns. Notwithstanding the restriction (or outright ban) on certain POEAs in Europe, Monsanto has continued to use relatively high-risk POEA surfactants in formulated products in the United States. As explained in a January 30, 2010 email, William Heydens stated that Monsanto continues to defend POEA surfactants because of concern over a "'domino effect' on etheramines; defend other world areas to the best of our ability," and that "they [Brazilian

Monsanto employees] are worried about this coming across the Atlantic to their part of the American hemisphere." (MONGLY02062439). Heydens was responding to a January 25, 2010 email from his colleague Richard Garnett on the question of whether to phase out known, high-risk POEA surfactants. After discussing some new studies underway on an alternative surfactant, Garnett wrote: "Anyway, there are non-hazardous formulations so why sell a hazardous one?" (emphasis added; MONGLY02062440). In my opinion, Garnet was correct in stating that less hazardous surfactants could be used in GBH formulations, including safer surfactants that Monsanto had previously procured and tested, and used in some Roundup products manufactured for sale in Europe (but not in the U.S.).

260. In a June 8, 2010 email regarding Roundup formulations containing POEA surfactants in Argentina, William Heydens wrote to Monsanto colleagues in Argentina: "So I would think that a backup plan of reducing POEA content is not sufficient, but rather a POEA-free formulation (or formulations) would be necessary to totally protect your business in Argentina." (MONGLY02013061).

261. In the slide deck prepared for "Regulatory Leadership Meetings" in November 2010, a slide addresses the business impact of the loss of POEA surfactants. "Germany is major concern" noting that "restrictions on POEA uses pre-harvest had significant negative impact on sales in 2010." (MONGLY02721133).

262. The "Strategy in Germany" included three core elements: (1) defend POEAs; (2) register non-POEA formulations; and (3) "Managed exit from POEA" to "Avoid a ban"; "Focus: voluntary non-renewal of registrations (e.g. MON 14420 and 2012)"; and, (3) "No sales of any POEA products after 2012." (MONGLY02721133).

263. Around year 2000, the European Commission put in place a new set of testing

guidelines to assess the degree to which formulated pesticides have the potential to disrupt the functioning of the endocrine system. Such chemicals are generally referred to as "endocrine disruptors" and can raise new types of human risks.

264. The U.S. Congress directed the EPA to assess the potential of pesticides to disrupt the endocrine system in a provision included in the 1996 Food Quality Protection Act.

265. In April 2002 Monsanto employees in Europe reported to headquarters that European regulators were working on development of a list of possible endocrine disrupting pesticides, and that some new assays might be required on glyphosate and/or formulated Roundup herbicides.

266. In response to this news, William Heydens sends an email at 7:20 a.m. on April 25th to Donna Farmer. In it, he suggests a call to "…to see if there is anything more we should be doing besides the usual 'pay no attention to the man behind the curtain'." He ends this email by saying "…this damn endocrine crap just doesn't go away, does it."

267. Farmer replies to Heydens at 8:19 a.m. and writes that the "interest[ing] point" is that published tests of possible glyphosate-endocrine disruption show that pure glyphosate has no effect, but formulated product (i.e. Roundup) does." (MONGLY00885551).

268. In response to Farmer, Heydens responds at 10:47 a.m. the same day, and reports that after discussions with other Monsanto experts, they: "…concluded, not surprisingly, that we are in pretty good shape with glyphosate ***but vulnerable with surfactants***." (Emphasis added).

269. In my opinion, Monsanto failed to address this admitted vulnerability, which the company could have, and should have done by carrying out the genotoxicity studies on formulated Roundup products recommended by Dr. Parry, as well as long-term oncogenicity feeding studies exposing mice and rats to a widely used Roundup formulation, instead of just

pure glyphosate.

## VI. Bio/dynamics Mouse Oncogenicity Study Triggers "Possible Oncogen" Classification

270. Based on the flawed, long-term glyphosate cancer study in rats conducted by IBT in the 1970s, OPP initially classified glyphosate as "not oncogenic in the rat" in or around 1977. This classification remained in place until EPA's March 4, 1985 "Consensus Review of Glyphosate" classified glyphosate as a category C, possible oncogen.

271. Throughout the 1977-1983 period, there was rapid growth in the number of approved tolerances and registered agricultural uses of Monsanto's glyphosate-based herbicides, despite the lack of a valid set of required, long-term feeding studies in mice and rats.

272. A new mouse oncogenicity study on glyphosate was among the IBT replacement studies submitted by Monsanto to OPP (EPA Accession #: 251007-014; Bio/dynamics Project No. 77-2061). It was conducted by the contract laboratory Bio/dynamics to fill a pending data gap, and was submitted to EPA on July 29, 1983.

### A. Results of Bio/dynamics Mouse Oncogenicity Study

273. The study followed routine design protocols for a chronic feeding study. There were four groups of Charles River CD-1 mice: control, 1,000 ppm glyphosate technical in the animals' diet, 5,000 ppm, and 30,000 ppm. There were 50 male mice and 50 female mice in each group. Animals were observed twice daily, and mortality during the study was reported as "normal for this age and strain of mice." (MONGLY04275682)

274. In the section "Results" in its summary report to Monsanto, Bio/dynamics states: "No treatment-related effects were demonstrated." In other words, the study was "negative" for oncogenicity.

275. But the Bio/dynamics summary report does address a number of statistically significant increases in tumors observed in the study. Table 1 in the report lists four "microscopic

changes" that were elevated in the treatment groups in a statistically significant way: central lobular hepatocyte hypertrophy (elevated in male mice), central lobular hepatocyte necrosis (elevated in males), chronic interstitial nephritis (elevated in males), and proximal tubule epithelial basophilia and hypertrophy (elevated in females).

276. Bio/dynamics dismisses all four types of lesions noted in their Table 1 by saying "All these findings, however, were of the type and severity common to long-term mouse studies."

277. The report also stated:

> "The incidence of renal tubule adenomas was 0/49, 0/49, 1/50, and 3/50, in control through high-dose males, respectively. This lesion, however, was not observed in any of the female treatment groups, and, as mentioned previously, this data was not statistically different from control. While not observed in control animals in this study, renal tubule adenomas have previously been observed in control male CD-1 mice of comparable age. ***The slightly increased incidence of adenomas in the high-dose males was considered spurious and unrelated to glyphosate administration***."
>
> (Emphasis added; MONGLY04275683)

278. In the male mice, the incidence of renal tubule adenomas reported by Bio/dynamics was 0/49 in the control group, and 0/49, 1/50, 3/50 in the three treatment groups (1,000 ppm, 5,000 ppm, 30,000 ppm). This increase in renal tubule adenomas showed a statistically significant upward trend.

**B. Review of the Bio/dynamics Mouse Study**

279. The importance of OPP's evaluation of the Bio/dynamics mouse oncogenicity study on glyphosate was widely recognized inside EPA and Monsanto, and in the pesticide regulatory community, and markedly heightened if the agency determined that the study was "positive."

280. Such a judgement would reverse the status quo classification of glyphosate as

"not oncogenic," and would have significantly altered the outcome of a number of pending and forthcoming tolerance petitions and registration applications in the U.S.

281. Two memos dated January 31, 1984 were sent from Monsanto toxicologist Lyle Gingerich to four colleagues (MONGLY04269118; MONGLY04269119-20). The first memo reports on a recent conservation Dr. Gingerich had with Robert Taylor.

282. Taylor was the senior official in OPP's Registration Division responsible for managing the flow through OPP of glyphosate-Roundup herbicide tolerance petitions and registration applications, as well as managing interactions between Monsanto and OPP on the fulfillment of data requirements, label changes, data compensation, and other issues that arise regarding the regulatory status of Monsanto's glyphosate-based herbicides.

283. In the first 1/31/1984 memo, Dr. Gingerich reports on presumably separate, face-to-face meetings on January 31, 1984 at OPP with Robert Taylor of the Registration Division and W.L. Burnam, Deputy Director of the Hazard Evaluation Division.

284. The Gingerich memo reports that Mr. Taylor told him that W.G. Dykstra of the OPP toxicology division had reviewed the new mouse oncogenicity study done by Bio/dynamics. The memo states: "R.J. Taylor said that he saw something in writing to indicate that when the review is sent to him it will state that Roundup is an oncogen."

285. The memo goes on to report that according to OPP's Mr. Taylor, various pending tolerance petitions will be denied, as a result of this change in OPP's characterization of glyphosate's oncogenic potential and the Delaney Clause-prohibition against approval of certain Section 409 tolerances.

286. Dr. Gingerich reports in this first of two January 31, 1984 memos that he intends to speak later the same day, again, with R.J. Taylor and W.L. Burnam of the toxicology branch,

in order to request "W.G. Dykstra's review and [discuss] what would be an appropriate forum for Monsanto inputs."

287. The first of two 1/31/1984 Gingerich memos to colleagues closes with this question: "Do you think it would be appropriate for our legal department to caution EPA on possible premature leaks of this review's conclusions prior to Dr. Kasza's [senior OPP pathologist] re-review and final disposition of the matter?"

288. Later in the day (January 31, 1984), Dr. Gingerich either met with, or spoke on the phone again with W.L. Burnam of the OPP toxicology branch, according to the second of two memos he sent to Monsanto colleagues and in which Gingerich passes along what Burnam had told him:

> "A 'complete' review of the glyphosate mouse study has not been done. There has been no section or branch sign-off of W.G. Dykstra's review. The question of kidney tumors was pointed out by W.G. Dykstra and is being evaluated by either C. Chaisson or Dr. L. Kasza. W.L. Burnam asked that we send in historical control data to document the claims made in our summary. He cautioned that these be from the same laboratory and time period. He said to be sure to report the numbers study by study, rather than as an overall average."

289. This second 1/31/1984 memo goes on to say that "R.J. Taylor continues to be concerned that Roundup actions will be held up for a few months until this is resolved." By "this," Dr. Gingerich is referring to the classification of glyphosate as a possible oncogen, an OPP action that would impact several pending OPP tolerance decisions.

290. The above series of events on January 31, 1984 are remarkable. On the same day during which Monsanto first learned that OPP's evaluation of the Bio/dynamics mouse study was likely to lead to a "possible oncogen" classification, a representative of Monsanto stationed in the company's Washington D.C. office (Dr. Gingerich) had:

- At least two face-to-face meetings with senior representatives of the OPP Registration and Toxicology Divisions;

- At least two follow-up calls or meetings with these same individuals; and
- Received a substantive request from Dr. Burnam for more data relevant to the primary issue explaining why Monsanto and OPP reached different conclusions regarding the results of the Bio/dynamics mouse oncogenicity study (the number of kidney tumors in the control group of male mice).

291. On February 10, 1984, Hoyt Jamerson of the OPP Registration Division received a memo from William Dykstra of the Toxicology Branch addressing the results of the recently submitted Bio/dynamics mouse study. Under "Recommendations," it states: "Review of the mouse oncogenicity study indicates that glyphosate is oncogenic, producing renal tubule adenomas, a rare tumor, in a dose-related manor. Therefore, Toxicology Branch considers that the PP#3E2845 [a pending tolerance petition] is not toxicologically supported."

292. The conclusion set forth in the February 10, 1984 memo is the first written confirmation that I know of stating that OPP now regarded glyphosate as a possible oncogen.

293. On March 20, 1984, Monsanto submitted to OPP historical control data on the incidence of renal tubule adenomas in the control groups of CD-1 mice in past studies.

294. OPP's Burman had suggested Monsanto submit historical control data from the same laboratory, and roughly from the same time period (i.e. within 3-4 years of the time the glyphosate mouse study was conducted). Monsanto submitted such historical control data from Bio/dynamics, as well as from two other "major" contract laboratories. (MONGLY04276057).

295. The final memo codifying Dykstra's review of the mouse oncogenicity study was sent to Taylor in the Registration Division on September 4, 1984. In its "Recommendations" section, the Toxicology Division states that "1. Glyphosate was oncogenic in male mice causing renal tubule adenomas, a rare tumor, in a dose-related manner. The study is acceptable as core-minimum data. 2. A [cancer] risk assessment by Toxicology Branch is required."

296. On February 5, 1985 Monsanto sent the Director of the OPP Registration Division

a letter advancing several arguments in support of the company's conclusion that the renal tubule adenomas in the male mice were not treatment related, nor statistically significant.

297. The 2/5/85 Monsanto letter sets forth six arguments in support of the company's assertion that the observed renal tubule adenomas were not treatment related: (1) tumors were only observed in male mice, (2) renal tubule adenomas were only present at the end of the study, suggesting they were caused by the age of the male mice, rather than exposure to glyphosate in the animal's feed, (3) only benign tumors were observed, (4) another Bio/dynamics, 2-year chronic feeding study in the same strain of mice with N-nitrosoglyphosate (NNG) produced no renal tubule adenomas in any control or treatment group, (5) glyphosate was not mutagenic in a number of assays, and (6) a statistical argument suggesting that the dose-related increase in renal tubule adenomas in the male mice was not statistically significant.

298. Toxicology Branch scientists assessed the data and arguments in this Monsanto letter prior to deciding whether to re-open their consideration of the renal tubule adenoma data. The review was conducted by Herbert Lacayo. After his statistical analysis of the data, he concluded that "a prudent person would reject the Monsanto assumption that Glyphosate dosing has no effect on kidney tumor production" (2/26/1985 memo, Lacayo to Reto Engler).

299. The OPP held a meeting on February 11, 1985 attended by eight senior scientists in the Toxicology Branch to specifically address the appearance of renal tubule adenomas in the male mice. The 2/11/85 meeting's stated purpose was to "evaluate and discuss the data base on Glyphosate, and in particular the potential oncogenic response of Glyphosate." The attendees reviewed the OPP assessment of the new mouse study, as well as the arguments and data submitted by Monsanto in its February 5, 1985 letter.

300. The attendees concurred unanimously that: "In accord with EPA proposed

guidelines (FR of Nov. 23, 1984) the panel has classified Glyphosate as a Category C [possible] oncogen."

301. On February 21, 1985, a Monsanto-requested meeting was held with the OPP Toxicology Branch (TB), attended by the TB Chief Ted Farber and then-Assistant Chief Bill Burnam. Dr. Gingerich, Frank Serdy, and Fred Johannsen represented of Monsanto.

302. A February 22, 1985 memo from Dr. Gingerich to Monsanto colleagues characterized the meeting mood as "relaxed, informal, and open." The memo states that Dr. Farber called the February 11, 1985 decision by OPP to classify glyphosate as a possible oncogen "an extremely close call and that EPA remains open to any new information that would make their decision easier." (MONGLY04269072).

303. The memo sets forth Monsanto's goals for the meeting, including: "(1) see if we could respond to their concerns [the renal tubule adenomas] before any unnecessary comments became a part of the Roundup permanent file. (2) determine exactly what their concerns are. (3) gauge the level of their concern."

304. Under the heading "Concerns of Toxicology Branch" in Gingerich's February 22nd memo, he reports that Dr. Farber opened the meeting by describing the conclusions of the OPP toxicology branch review of the mouse oncogenicity study. Specific points noted were: "Oncogenic in mouse, IARC ranking 'c' [possible human carcinogen]; Company's letter [Monsanto's February 5th letter] was too weak to be convincing; Biologically significant rare tumors; Historical controls [data] not helpful; Will ask to re-section tissues, consider crystal formation, etc."

305. The meeting memo then states that "Dr. Farber indicated that a substantial re-look at tissues may cause the EPA pathologist [Dr. Kasza] to change his position. If no carcinomas are

found the second time, our arguments about 'only benign' tumors would be stronger. I [Gingerich] read this to mean that the EPA pathologist (Kasza) is open to persuasion."

306. Next, the memo reports on several questions raised during the meeting, and their answers. Monsanto representative FJ (Frank Johannsen) then asked OPP's Dr. Farber "…what the EPA would be likely to do if we [Monsanto] re-sectioned the slides and found no carcinomas. Dr. Farber said that it would force them to get the internal peer review group together again."

### C. OPP Dismisses Monsanto's Historical Control Data Argument

307. On February 5, 1985, Monsanto sent to the Director of the OPP Registration Division a four-page letter transmitting additional information related to the Bio/dynamics chronic mouse study.

308. On February 26, 1985, an EPA memorandum was sent to OPP statistician Reto Engler, a senior scientist involved in the Toxicology Branch's review of glyphosate's oncogenicity. The memo was written by OPP statistician Herbert Lacayo, and sent through and signed off by Bertram Litt, OPP's Statistics Team Leader.

309. The memo focused on whether the additional, mouse historical control data for kidney tumors submitted by Monsanto should alter the OPP assessment of the significance of the reported renal tubular adenomas in the Bio/dynamics study. It begins by noting that Monsanto submitted "historical control data from Bio/dynamics and two other laboratories."

310. The summary of the Lacayo statistical review of the historical control data states that "…we can conclude that Glyphosate dosing has a statistically significant effect (at the $p = .006$ level) in the production of kidney tumors in male mice" (i.e., highly statistically significant, since the usual cut-off for significance is the $p = 0.05$ level).

311. A March 4, 1985 OPP memo on the subject "Consensus Review of Glyphosate" codified the conclusion reached by the eight Toxicology Branch scientists, each of whom signed the consensus review document. (MONGLY04269067). The signatories included the Chief of the Toxicology Branch Theodore Farber, OPP's senior pathologist who read the Bio/dynamics mouse study histopathology slides, Bertram Litt, OPP's senior statistician, and William Dykstra, author of the original OPP review of the mouse study.

312. The memo was sent to Robert Taylor in the Registration Division, and marked the end of the beginning of a protracted debate between OPP and Monsanto over the results of the Bio/dynamics mouse study.

**D. Monsanto Takes Its Case to the Director of the OPP Registration Division**

313. Only two days passed before Monsanto again wrote to OPP, this time to Douglas Campt, then Director of the OPP Registration Division. The five-page March 13, 1985 letter was sent by Frank Serdy, Monsanto's Manager, Federal and State Registration Affairs.

314. The letter recounts the recent history of OPP's evaluation of the Bio/dynamics mouse oncogenicity study, the numerous meetings and back-and-forth involving OPP and Monsanto scientists, and asserts that the renal tubule adenomas observed in the male mice in the study are not treatment related, nor statistically significant. It also restates the many Monsanto arguments advanced in support of the company's position over the past six weeks.

315. In closing his letter to Mr. Campt, Mr. Serdy states that:

> "As you know, glyphosate is an extremely important herbicide to agriculture in the U.S. and around the world. Monsanto is concerned that even the initiation of formal regulatory action would have serious negative economic repercussions which we believe are not justified by the scientific evidence."

316. In an April 3, 1985 memo from William Dykstra to the Registration Division's Robert Taylor, the Toxicology Branch's judgement regarding glyphosate's oncogenicity was

stated as it had been previously: “Glyphosate was oncogenic in male mice causing renal tubule adenomas, a rare tumor, in a dose-related manner.”

**E. Monsanto Hires Another Pathologist to Re-read the Kidney Slides**

317. Also, on April 3, 1985, Dr. George Levinskas, a scientist in the Monsanto Department of Medicine and Environmental Health, circulated a brief update inside the company stating that “Senior management at EPA is reviewing a proposal to classify glyphosate as a class ‘C possible human carcinogen’ because of kidney adenomas in male mice. [Private, consulting pathologist] Dr. Marvin Kuschner will review kidney sections and present his evaluation of them to EPA in an effort to persuade the agency that the observed tumors are not related to glyphosate.” (MONGLY04277789).

318. Dr. Kuschner had not been involved with the design, conduct, or evaluation of the Bio/dynamics mouse oncogenicity study and had not previously reviewed the study’s histopathology slides.

319. Also, on April 3, 1985, a letter was sent by Dr. Aleksanday Knezevich, Senior V-P, Pathology at Bio/dynamics to Dr. Marvin Kushner, a private consulting pathologist (MONGLY04269049). The letter informs Dr. Kushner: “The enclosed shipment is being sent to you at the request of Dr. Tim Long of Monsanto. It contains slides of kidney sections from all animals on the reference study [mouse oncogenicity study].”

320. Sometime in or around mid-May 1985, Kushner submitted his report to Bio/dynamics and Monsanto. The company reviewed the report, and submitted it to OPP. The report was, as predicted before Dr. Kushner even received the slides, supportive of an “effort to persuade the agency that the observed tumors are not related to glyphosate.”

321. In a June 14, 1985 memo from OPP’s senior statistician Reto Engler to Robert

Taylor of the Registration Division, Dr. Engler reports that after a TB peer-review process:

> "We have determined that the incidence of renal adenomas in male mice (a rare tumor) is inconsistent with the historical control incidence of this tumor. The registrant, in several letters, has refuted our statistical analysis of the data. Basically, the registrant contends that the highest incidence ever observed in historical controls should be used to judge the incidence in the Glyphosate study. The use of any historical control data in this manner is biologically as well as statistically inappropriate and misleading." (Underlining in original).

322. Then, Dr. Engler goes on to report that the registrant has now submitted a report "which shows that a re-reading of the kidney slides has revealed one (1) kidney tumor in the control group but no additional tumors in the treatment groups." In light of this new information, Engler writes that:

> "Given the overall uncertainty concerning the significance of the observed tumor incidence we believe a systematic reevaluation of this kidney lesion has become necessary in order to fully evaluate Glyphosate."

323. The Kushner report delayed EPA's final determination as to glyphosate oncogenicity in the Bio/dynamics study.

324. OPP's decision to re-section the slides also created the possibility that new information would emerge supporting Dr. Kushner's assessment of the slides, and/or changing the number of tumors in the male mice control and three treatment groups in a way that eliminates the dose-related response in the frequency of renal tubule adenomas. (MONGLY00235097 at 5412).

**F. Re-sectioning of the Bio/dynamic Mouse Kidney Slides**

325. "If the results of the kidney re-sectioning do not resolve the glyphosate issue within OPP, we will be faced with an adverse OPP decision," wrote Lyle Gingerich to Monsanto colleagues in an August 20, 1985 memo. (MONGLY04268982).

326. Gingerich also discusses the prospect that OPP might decide to place unresolved

science issues before the agency's Scientific Advisory Panel (SAP), especially if a deadlock emerges between the conclusions of Monsanto's and OPP's pathologists.

327. Gingerich goes on to ask "Can we change the focus of the question to the S.A.P. to: 'Is 30,000 ppm too high [a dose] to be used in a meaningful risk assessment?'…If we assembled 10 respected toxicologists, would all ten agree that the feeding level is too high to be meaningful?" He then suggests that the 10 toxicologists agreeing with Monsanto's position should be brought to the SAP meeting and asked to speak in support of the company's assessment of the mouse study, given "…the importance of this issue to Monsanto."

328. Gingerich then explains why he has suggested that all 10 toxicologists should be brought to the SAP meeting: "There is a tendency to 'count the votes' at S.A.P. meetings. We can make a difference by lining up a large number of experts on our side."

329. Eight days later, on August 28th, Frank Serdy, the Director of Federal and State Regulatory Affairs for Monsanto, wrote a memo to his colleague Tim Long, another official working on the effort to change EPA's mind on the mouse oncogenicity study. Serdy wrote on the topic of "Additional Steps" in the effort to change EPA's assessment on the Bio/dynamics mouse study. (MONGLY04268980).

330. He voices confidence that glyphosate will ultimately be shown to be not oncogenic but lays out some "additional steps" if the results of the re-sectioning of the kidneys does not change EPA's mind.

331. First, Serdy writes: "We continue to feel it is important to identify and contact those outside 'experts' who we feel would testify on our behalf both to EPA and SAP that, based on the results, glyphosate is not oncogenic."

332. Serdy's second "additional step" is prefaced by acknowledging that "We do not

have a lot of faith, presented with the same evidence, Ted Farber [senior OPP scientist in the Toxicology Branch] will want to back off and change his mind." Serdy then writes: "Hence we feel that it is equally as important to identify and contact 'experts' in the area of statistics who would be willing to testify both to the EPA and SAP that 1-0-1-3 cannot be considered statistically significant."

333. Note that in Serdy's second point he is assuming that EPA has, or will accept Dr. Kushner's conclusion that one mouse in the male control group had a renal tubule adenoma that was not detected or reported in the original Bio/dynamics report on the study. In the absence of that one, additional adenoma in the male mice control group, the tumor incidence would have remained as originally reported, 0-0-1-3, and reflect a trend which is unambiguously dose-related and highly statistically significant, as Lacayo's 2/26/85 memo had concluded.

334. Driving home the importance of these "additional steps," Serdy writes that:

> "It seems imperative that we continue to do all that is possible in order to have the Agency reverse its decision. Hopefully, the testimony of several respected 'experts' will be enough to cause EPA to change their minds."

335. The re-sectioning of the male mice kidneys, and the re-evaluation of the slides, was done by Bio/dynamics, at the request of Monsanto. The OPP pathologist Dr. Kasza had been consulted in the process of developing the procedures. R.F. McConnell, a pathologist consulting with Bio/dynamics, read both the original slides, and the slides from the re-sectioned kidneys.

336. The Bio/dynamics report covering the re-sectioned kidney tumors was dated September 26, 1985 and was submitted to the EPA a few days later.

337. The significant result in the Kushner-Bio/dynamics report is finding one renal tubule adenoma in the control group of male mice (mouse # 1028). The report states:

> "Confirmation of the diagnosis of the original renal tubular adenomas was made, including concurrence with Dr. Marvin Kushner on the presence of a lesion in the

> control group which represented a developing tumor. No new tumors were found in any of the [other] control or treated groups."

338. The report concluded: "The renal tumors observed were considered to be incidental and not toxicologically significant."

339. The technical response from the Toxicology Branch to the September 26, 1985 Bio/dynamics report was done by Dr. Kasza, OPP's senior pathologist, and the scientist who had been consulted by Bio/dynamics on the procedures to be followed in the re-sectioning of the kidneys. Kasza's December 4, 1985 memo was sent to William Dykstra, the lead reviewer of the mouse study in OPP's Toxicology Branch.

340. The single, critical question was whether Dr. Kasza agreed with Dr. Kushner and the Bio/dynamics pathologist Dr. McConnell that control male mouse #1028 had a renal tubule adenoma. Kasza requested and re-read the original slides for male mice, as well as the newly re-sectioned kidney slides. He found no differences in the number of renal tubule adenomas in the treatment groups.

341. In reference to the tumor in control group mouse # 1028 reported by Kushner and McConnell, Dr. Kasza wrote:

> "It is my opinion that the presence of a tumor cannot be definitely be established. My interpretation is similar to the conclusion of Bio/dynamics' pathology staff and Dr. McConnell, that the lesion 'may be' a proliferative change having the potential to lead to the development of a frank tumor. But as the tissue can be seen under the microscope as a small well-demarcated focal cell aggregate morphologically different from the healthy looking surrounding kidney tissue, this morphological alteration does not represent a pathophysiologically significant change."

342. Dr. Kasza's reading of the newly sectioned kidney of animal #1028 was that there was a group of cells that looked different and that might become a lesion of some sort, but the cell mass had not reached the stage justifying identification as a renal tubule adenoma.

### G. The 1986 SAP Review of the Mouse Oncogenicity Study

343. Kasza's interpretation was accepted within EPA. As a result, the EPA and Monsanto were again dead-locked.

344. A January 17, 1986 Federal Register notice announced a two-day SAP meeting on February 11-12, 1986 during which the Bio/dynamics mouse study would be evaluated. Agenda item 1 read: "Review of a set of scientific issues related to apparent oncogenicity being considered by the Agency in connection with the preparation of a Registration Standard for glyphosate."

345. Monsanto sent a January 23, 1986 letter to Steven Johnson, a senior EPA official who managed the SAP. After noting that the Federal Register notice said the SAP would assess glyphosate's "apparent oncogenicity," the letter stated that: "Monsanto firmly believes that glyphosate is not an oncogen, and we therefore do not agree with this position taken by the Agency. The Agency is in error in reaching this conclusion…"

346. The letter argues that the OPP determination does not follow EPA's Proposed Guidelines for Carcinogen Risk Assessment, and then adds:

> "In addition to Monsanto's own evaluation, this matter has been reviewed by five independent experts. The unanimous conclusion reached by these scientists is that there is no treatment-related oncogenic effect of glyphosate in the chronic mouse study…"

347. Recall the August 20, 1985 Gingerich memo discussed above. It suggested that Monsanto recruit 10 experts to testify before the SAP, and that "[t]here is a tendency to 'count the votes' at S.A.P. meetings." (MONGLY04268982).

348. The focus of the glyphosate oncogenicity discussion during the February 11, 1986 SAP meeting was on the histopathology of the kidney slides, and in particular:

- The number of tumors in the male mouse control group;

- The appropriate statistical analysis to use, and whether the renal tubule adenoma incidence reached statistical significance; and
- The proper use of historical control data.

349. The two questions presented to the SAP by the EPA were:

> "(1) Based on the Agency's weight of the evidence assessment with emphasis on the mouse kidney tumors, the Agency has classified Glyphosate as a class C (possible human) carcinogen. The Agency specifically requests any comment the Panel may wish to present with regard to its assessment of the weight of the evidence and subsequent determination of carcinogenicity according to the Agency's Cancer Guidelines."
>
> "(2) The Agency requests also that the Panel consider what weight should be given to this marginal increase in kidney tumors, the importance of this type of tumor in the assessment of the carcinogenicity of Glyphosate, and the weight placed on historical and concurrent controls for this type of evaluation."

350. The primary presentation by EPA was done by Dr. Farber, and Monsanto's presentation was made largely by Robert Harness, Director of Environmental and Government Affairs, Dr. Timothy Long, in the company's Medical Department, and Mr. Wayne Withers.

351. In addition, Monsanto brought to the SAP meeting, three experts who had been involved with the study and/or the reading of the controversial kidney slides: Dr. Marvin Kushner, the pathologist who re-read the original mouse study kidney slides; Dr. R.F. McConnell, the consultant to Bio/dynamics that read the original slides, as well as the re-sectioned slides; and Dr. Ira Daly, the Bio/dynamics laboratory director.

352. Each of these individuals brought to the meeting by Monsanto were given opportunities to make short presentations and participate in the Q & A with SAP members.

353. In addition, Monsanto announced to the SAP that they had submitted the data in question to a panel of four consulting experts (Squires, Olsen, Stemmer, Goodman), all of whom agreed with Monsanto's interpretation of the mouse oncogenicity study results. These experts were also in attendance and participated in the Q&A.

354. One of the invited experts – Dr. Don Goodman – was asked by Monsanto to attend and represent the conclusions of a second review panel convened at the request of Monsanto by Pathco Inc, a pathology consulting group. The Pathco panel reviewing the same mouse oncogenicity data included five scientists (Sourer, Anver, Stranberg, Ward, Goodman).

355. In his opening statement to the SAP, Harness summarizes the key conclusions reached by each of the Monsanto-invited experts, as well as the expert panel convened at Monsanto's request by Pathco Inc.

a. Dr. Marvin Kushner, found an additional tumor in the male mouse control group, no additional tumors in the treatment group, switching the study from purportedly positive to negative for renal tubule adenomas. His concluding statement, quoted by Harness, is that "I see no reason to assign carcinogenic potential to glyphosate."

b. Robert Squires, "In summary, I feel the weight of the evidence strongly suggests the renal adenomas in male mice were naturally occurring and not treatment related."

c. Robert Olsen, "In summary, it is my view that these findings do not support the view that [text cut off]."

d. Dr. Robert McConnell, "It is and has been the opinion of this pathologist that the tumors were incidental and were not toxicologically significant."

e. Dr. Klaus Stemmer, "The incidence of renal tubule adenomas is in all probability biologically by chance."

f. Pathco Inc panel (Drs. Sourer, Anver, Stranberg, Ward, and Goodman, who represented the panel at the SAP meeting), "The incidence of renal

tubule cell neoplasms in this study are not compound related."

g. Monsanto's Dr. Timothy Long provided an overview of the back and forth over the mouse study pathology results, and then summarized Monsanto's position by stating, "The overall incidence [of renal tubular adenomas], therefore, remained at 1-0-1-3. These [kidney section] slides and/or supporting data have now been reviewed by a total of 10 pathologists and toxicologists and the unanimous conclusion of all the experts is that there is no evidence of any treatment related oncogenicity."

356. Accordingly, the Monsanto team offering conclusions and presenting data before the SAP included 14 people: three from Monsanto, three individuals involved with the study, four consulting experts, and four additional experts who joined Dr. Goodman (in attendance) on the Pathco Inc panel.

357. The report providing the SAP panel's answers to the two questions EPA asked the panel to address on February 11, 1986 was transmitted to the Director of OPP on February 24, 1986 and released publicly soon thereafter. The section "Panel response" begins by saying: "In the instance of Glyphosate, the Panel concurs that the data on renal tumors in male mice are equivocal."

358. The SAP report goes on to state: "The vast majority of the pathologists, who examined the proliferative lesion in the male control animal, agreed that the lesion represented a renal adenoma. Therefore, statistical analysis of the data should utilize this datum."

359. This conclusion that the "vast majority" of pathologists agreed with the Monsanto interpretation stands in contrast to a statement made by the EPA in its assessment of the differing views on whether control animal #1028 had a renal tubule adenoma.

360. In Dr. Faber's presentation to the SAP, he states: "we [EPA] do see an increased incidence statistically…" On the critical issue of whether there was a renal tubule adenoma in control mouse #1028, Dr. Farber's offered his accounting of the differing views: "…perhaps three pathologists saying no [tumor], perhaps four or more pathologists saying yes."

361. The person representing Monsanto at the SAP meeting was Robert Harness, Director of Environmental and Government Affairs. In his opening comments to the SAP, Harness said: "Because glyphosate is the largest selling herbicide in the world, with many registered uses, we consulted a group of scientists to advise us ***on the questions raised by the EPA and presented to you by Dr. Farber***." (Emphasis added)

362. The three individuals at the SAP meeting supporting the conclusion that there was "no tumor" in control animal #1028 were EPA scientists (Faber, Kasza, Lacayo), while the remaining 14 scientists stating that there was a tumor were working for, or hired by, Monsanto.

363. Taking into account the uncertainty over the number of renal tubule adenomas, the use of historical controls, and the statistical methods used to judge whether the observed tumors were treatment related, the SAP's final judgement was equivocal:

> "…the Panel does not believe that it is possible to categorize Glyphosate clearly into Group C (possible human carcinogen) or Group E (no evidence of carcinogenicity in humans). The Panel proposes that Glyphosate be categorized as Group D (not classified) and that there be a data call-in for further studies in rats and/or mice to clarify unresolved questions."

364. On August 11, 1986, OPP issued the glyphosate Registration Standard (RS) document setting forth guidance to companies seeking to register new or retain existing pesticide product labels for herbicides containing glyphosate (the date on the RS document is June 1986; it was released on 8/11/86 date). (MONGLY00223577).

365. In 1986, Monsanto was the sole manufacturer of glyphosate-based herbicides, so

guidance in the 1986 RS document regarding steps that manufacturers of glyphosate herbicides must take was guidance to Monsanto, and all responses to the RS by industry, and actions taken and not taken, were Monsanto actions/inactions.

366. The RS document is a key historical milestone in the EPA's assessment of glyphosate uses, risks, and benefits, as well as with respect to actions that the EPA then regarded as essential to assure that the benefits stemming from Roundup uses will routinely exceed any risks.

367. Key functions of the 1986 RS review and document were to specify required labelling statements and precautions that must appear on product labels, and alert companies to the studies that they must agree to commission and submit to the agency in a timely way in order to retain existing registrations/product labels or win approval of new uses/labels in the future.

368. The 1986 glyphosate RS document states on page 2: "Failure to comply with these requirements [e.g. filling data gaps, adding new worker safety rules] may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data)."

369. Under the heading "Chronic Feeding/Oncogenicity Data," the glyphosate Registration Standard notes that available studies included a 2-year mouse and rat chronic feeding studies and a 1-year dog study. But because of limitations in study design and/or questions over the interpretation of equivocal results, none of these studies satisfied core, OPP chronic feeding study data requirements.

370. Hence, the "Summary Science Statement" in the Registration Standard states that "Repeat oncogenic studies are required in mice and rats." (Page 5).

371. EPA required the company to repeat the invalid IBT rat oncogenicity study that,

among other things, failed to reach the Maximum Tolerated Dose ("MTD") in the high-dose treatment group (maximum doses in long-term feeding studies are supposed to come close to the MTD).

372. About three weeks after the public release of the glyphosate RS, Frank Serdy, the head of product registrations at Monsanto, sent a memo to Monsanto colleagues involved in the ongoing debate over glyphosate oncogenicity. In this August 28, 1986 memo, Serdy outlines "suggestions" for Monsanto's response to the Registration Standard's data call-in for repeat mouse and rat oncogenicity studies. (MONGLY04278162).

373. After describing possible Monsanto arguments to EPA challenging the need for repeat studies, Serdy writes:

> "If successful [EPA drops the requirement], this approach has the following downside: EPA's response may be: 'Fine, don't repeat either study. We will just put you into class C [a possible oncogene under EPA's classification system][.]'"

374. Soon after the release of the glyphosate RS document in August 1986, Monsanto communicated to EPA via several channels its disagreement with some of the actions required by EPA in the RS document.

375. Serdy asserts in a RS-response letter to OPP that:

> "The results of the mouse bioassay do not provide positive, or even suggestive, evidence of carcinogenicity. The most that can be said is that the results were equivocal as, in fact, the Scientific Advisory Panel stated."

376. In this letter, it notes that the company had asked several consulting experts to testify at the SAP meeting, with their time and expenses paid for by Monsanto. The Serdy letter states that the experts "were asked to evaluate the need for a repeat study. All experts agreed that additional testing is not justified…" (page 2).

377. I carefully reviewed the verbatim transcript of the testimony of the experts

brought to the SAP meeting by Monsanto, and their interactions with the SAP. None of them spoke to the issue, or expressed an opinion about whether the mouse study should be repeated, as Serdy had claimed in his letter to OPP.

378. In accord with routine OPP procedures, Monsanto's scientific arguments and requests for waivers of RS data requirements, including a repeat mouse study, were reviewed by the relevant branches of OPP.

379. Monsanto had formally requested waivers for two study requirements in the RS document: (1) an LC-50 inhalation study, and (2) a repeat mouse chronic feeding/oncogenicity study. William Dykstra in the Toxicology Branch reviewed the request, and Monsanto's supporting data. He prepared the Tox Branch memo regarding "Glyphosate – Monsanto Comments to Glyphosate Guidance Document." (MONGLY00223052).

380. Dykstra concurred/approved waiver request (1). On request (2), he wrote: "TB [Toxicology Branch] does not concur with Monsanto regarding the waiver of the repeat mouse oncogenicity study (see discussion in review section [pages 3-6 of the memo])."

381. In his review of Monsanto's arguments in support of a waiver for the mouse study, Dykstra wrote: "Regarding the need to repeat the mouse oncogenicity study with glyphosate, TB fully concurs with the conclusion and recommendation of the Scientific Advisory Panel (SAP)." The SAP had concluded that glyphosate be classified as Group D (not classifiable as to oncogenicity) and recommended that replacement studies in mice and/or rats be carried out.

382. He then writes: "TB believes the oncogenic potential of glyphosate in mice still remains unresolved and that a repeat mouse study is necessary to fully and adequately assess this potential." (MONGLY00223052)

383. Dykstra's memo goes on to say that the new mouse oncogenicity study should be

"specially designed" to clarify "certain unresolved questions relating to the potential oncogenicity of glyphosate."

384. Dykstra's set forth several specific study requirements. First, he recommended retaining the 30,000 ppm high-dose treatment rate, since survival in that group of male mice exceeded survival in the control group. Second, he recommended that two additional treatment groups should be added to more definitely delineate whether there is a dose-response – 7,500 ppm, and 15,000 ppm. Third, there should be 200 male mice per group, to enhance statistical power.

385. Dykstra proposed concessions to reduce the cost of the repeat study. He stated that the study should focus only on unresolved questions from the first study, and only on male mice (cutting the number of animals in half). He also proposed a "tier approach" in the pathology examination phase of the study, focusing first on kidney and liver sections in all groups of male mice. If the "first tier" examination produces no evidence of an oncogenic response, "then additional histopathological examination will not be necessary."

386. Monsanto continued to resist EPA's call for a new mouse oncogenicity study and has still not redone the Bio/dynamic study nor carried out the special study requested by EPA.

387. In my opinion Monsanto should have conducted the special study requested by EPA in response to the agency's request, and in light of the company's commitment to product safety. I also conclude that, and in the interim, Monsanto should have added an oncogenicity warning (e.g., "…exposures to this product may increase the risk of certain cancers…") to Roundup labels, as well as in GBH chemical safety data sheets and other information developed for physicians and poison control centers.

## VII. Monsanto Does Not Add New Worker Safety Language on Roundup Warning Labels

388. The 1986 glyphosate Registration Standard ("RS") specified new worker safety language that must appear on Roundup product labels in channels of commerce as of June 30, 1988.

389. In a February 9, 1987 letter to the Director of the OPP Registration Division, Monsanto asserted that the worker-protection language in the 1986 RS is unjustified, for reasons first set forth in Monsanto's November 7, 1986 response to the RS.

390. The 2/9/87 letter restated and expanded upon the arguments set forth in the 11/7/86 letter. The February 1987 letter also transmitted to OPP a new contact-dermatitis study done by a University of California scientist.

391. OPP's review of the February 1987 letter, the actions it requested, and the newly-submitted dermatitis study was done by Curt Kunchick, a scientist in OPP's Exposure Assessment Branch. His June 18, 1987 review notes that the focus of Monsanto's arguments is contact dermatitis and the newly submitted dermatitis study, while OPP's principal concerns were eye and skin irritation. (MONGLY00241308).

392. There are three important attachments included with Kunchick's 6/18/87 review: (1) a report on glyphosate poisoning episodes in California, (2) "Worker Safety Rules for Glyphosate Products Containing the Signal Word 'Warning' for Skin or Eye Irritation"; and, (3) "Worker Safety Rules for All Glyphosate Products Intended for Agricultural Uses and Containing the Signal Word 'Caution'".

393. The required worker-safety protection statements in Attachment 2 to Kunchick's memo were taken verbatim from the 1986 Registration Standard section setting forth "Required Labelling" (page 28-29).

394. Attachment 1 was the primary basis for OPP concern over eye and skin irritation. It included data submitted to EPA by the California Department of Food and Agriculture in a June 6, 1988 report entitled "Glyphosate Poisoning Statistics Summary." The author was Jerome Blondell.

395. Data were recorded by Blondell for three categories of applicators: ground application using a tractor or spray rig (42 out of 143 total cases); hand application with a backpack sprayer or hand-pump device (100 out of 142 cases); and, other types of application (1 of 142 cases).

396. Blondell's data covered 64 applicator, and 24 mixer/loader, cases of eye irritation between 1981 and 1985, and 52 applicator and 7 mixer/loader skin injury cases. In addition, there were a total of 24 "Systemic" illnesses reported, 6 cases among spray rig applicators and 18 among hand applicators. Hand applicators had suffered the majority of total-applicator injury cases: for the eye, 44 out of 64, and for skin, 35 of 52 irritation cases.

397. A section of Blondell's report addresses the relationship between the number of physician-treated occupational illnesses in California and the total pounds of glyphosate applied. The Blondell report contains the following finding:

> "The number of California physician-treated occupational illnesses (average per year, 1981-1985) per million pounds of glyphosate reported sold in California in 1984 was 17.0. On average, for all pesticides, we find 1.3 poisonings per million pounds sold, per year in California."

398. Section D, Part 4 of the glyphosate RS states that "Worker Safety Rules must appear on end-use products containing glyphosate except for those labeled for homeowner use only." (page 28).

399. EPA required worker-safety provisions on glyphosate products include:

"HANDLE THE CONCENTRATE ONLY WHEN WEARING THE

FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT."

"Wear goggles or a face shield, chemical resistant gloves, chemical resistant apron, chemical resistant shoes, shoe coverings, or boots."

"WEAR THE FOLLOWING PROTECTIVE CLOTHING DURING APPLICATION, EQUIPMENT REPAIR, CLEANING, DISPOSAL OF THE SPRAY SOLUTION, AND DURING REENTRY TO TREATED AREAS BEFORE THE SPRAY HAS DRIED."

"Wear goggles or a face shield, chemical-resistant gloves and chemical-resistant shoes, or boots. A helmet with visor may be worn during open cockpit aerial application."

"IMPORTANT! Before removing gloves, wash them with soap and water. Always wash hands, face and arms with soap and water before smoking, eating, drinking, or toileting."

"AFTER WORK, wash protective clothing and equipment with soap and water after each use. Personal clothing worn during use should be laundered separately from household articles. Clothing or protective equipment heavily contaminated or drenched with glyphosate must be disposed of in accordance with State and local regulations."

"HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED." (Page 29, glyphosate RS)

400. In late 1986 and 1987, OPP was working on a policy document setting forth new worker-safety requirements for product labeling that would apply to all registered pesticides. OPP planned on issuing the new worker-safety labeling requirements via what is called a Pesticide Regulatory ("PR") Notice.

401. The worker-safety protections for applicators called for in the 1986 RS were supposed to appear on all Roundup-product labels in commerce as of June 30, 1988. However, in a 11/2/87 letter to Robert Taylor, OPP's registration manager for glyphosate, Monsanto requested a postponement of certain additional protective clothing requirements on Roundup labels.

402. EPA assigned the task of reviewing and responding to this Monsanto request for

deferral to Alan Nielsen in OPP's Exposure Assessment Branch. He received the assignment on 11/18/87 and a memo setting forth his recommended action is dated 1/28/88.

403. Nielsen agreed to Monsanto's request to postpone additional requirements for personal protective equipment (PPE) on Roundup labels subject to two conditions. The first was that the new worker-protection PR notice would be issued "…in a reasonable time frame…", and lead to changes in Roundup worker safety language compared to those required in the RS. And second, "…the submitter [Monsanto] begin investigating the high number of eye and/or skin injuries associated with glyphosate use in California."

404. Reinforcing his concern, Nielsen added in his memo to the Registration Division that: "Myself and other members of the Exposure Assessment Branch would like to meet with appropriate representatives of the Monsanto Company to discuss their response to this concern [the adverse impacts data from California] within six months. Please arrange with the submitter."

405. Monsanto continued to challenge EPA's requirements for stricter worker-safety provisions through multiple communications over several years. Some arguments were procedural (e.g., defer changes in labeling until the new, generic worker-safety labeling PR notice was issued), while others were supported by references to Monsanto-commissioned exposure studies and risk calculations.

406. Ultimately, Monsanto never added the language requested in 1986 calling for use of new Personal Protective Equipment (PPE) and other steps to reduce worker exposures. The labels for Roundup products generally state: "Personal Protective Equipment (PPE) Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks…[no other PPE is required]"

407. The phrase "other handlers" encompasses those mixing and loading, shipping,

storing, or handling the herbicide.

408. The label requires that PPE be kept and washed separately from other laundry, and then provides this instruction to applicators and other handlers:

> "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with ***this product's concentrate***. Do not reuse them." (Emphasis added).

409. Accordingly, "clothing and other absorbent materials" drenched with Roundup ***spray solution*** need not be discarded, despite EPA stating in the 1986 RS that heavily contaminated clothing cannot be fully decontaminated and should therefore be discarded.

410. Under the heading "User Safety Recommendations," the label states that "Users should:

> "Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

411. There is also a "Non-Agricultural Use Requirement" on each label: "Keep people and pets off treated areas until spray solution has dried." There are no other sections or provisions on Roundup labels that address the need, or ways to reduce worker exposures and risks.

412. To this day, Monsanto has not added to Roundup product labels the worker-safety precautions and requirements as set forth in the 1986 RS. In my opinion, a reasonable and prudent pesticide manufacturer would have added this common sense warning language to the label. Monsanto, to this day, never has.

413. Throughout the 1990s and 2000s, there was a steady flow of new information regarding worker risks from: (a) Monsanto's ongoing research and testing around the world that pointed to the need to address high-exposure scenarios and eliminate high-risk surfactants, and

(b) exposure and illness episodes reported to the 1-800 phone numbers on Roundup labels, in the event of the need for emergency medical assistance.

414. Regulators in the UK required Monsanto to add a requirement for respiratory protection on certain Roundup labels, as a result of high-exposures around the face when Roundup is applied to trees via a backpack sprayer. (MONGLY06454420).

415. The EU had been pushing for years for the removal of POEA surfactants from Roundup formulations, a task that Monsanto worked to achieve in European formulations throughout the 2000s and pledged to complete by 2012.

416. But in the U.S., Monsanto blocked or curtailed more restrictive worker-safety language on most formulated product labels and retained POEA surfactants in essentially all products.

417. Richard Garnett, a European-based Monsanto scientist, sent a November 10, 2008 email to his Monsanto colleagues Saltmiras, [redacted] Farmer, and [redacted]. In it, [redacted] shares his view that Monsanto needed to conduct additional studies to obtain better data to address worker-exposure concerns across Europe. (MONGLY02155826).

418. The new data and analyses that [redacted] was advocating would be included in an Annex to the dossier Monsanto was developing for submission to the German regulatory authority, as part of the re-registration of glyphosate in the EU.

419. In his email, Garnett writes: "Dermal exposure is the greatest risk of exposure to operators. Therefor we need to be secure on the ADME of such exposure." ADME stands for **A**bsorption, **D**istribution, **M**etabolism, and **E**xcretion. (MONGLY02155827).

420. A few days earlier (November 7, 2008), [redacted] had sent an email to Monsanto colleagues, including [redacted], a Monsanto employee based in Germany who was

interacting with the BfR on glyphosate re-registration issues. [redacted] 11/7/2008 email outlines the topics of discussion on a call addressing adverse worker-exposure episodes the BfR was aware of. Four areas of "preparation" for future interactions with BfR were outlined, including: "3. Toxicology: counter the allegation on synergistic effects of tallow amine [POEA surfactants] with glyphosate." (MONGLY010122033).

421. Regulators in Italy and Germany were, in particular, concerned over data published in peer-reviewed journals showing that Roundup products formulated with POEA surfactants pose greater risks than glyphosate alone. Monsanto asked Dr. Parry to review several of them. Recall, as well, Heydens' comment quoted previously that, not surprisingly, "we are in pretty good shape with glyphosate [re genotoxic risks] ***but vulnerable with surfactants***."

422. The EPA has based its glyphosate worker-risk assessments on data provided predominantly by Monsanto. If the data from Monsanto is not current or is inaccurate, regulatory risk assessments will also be inaccurate, and hence may poorly reflect actual risks in the field.

423. In my opinion, the failure of Monsanto to generate and submit to the EPA updated, more accurate worker-exposure and worker-risk data based on use of, and exposures to GBHs perpetuated EPA reliance on out-of-date, inaccurate worker-risk assessments that almost certainly underestimated actual risks.

424. A published, peer-reviewed genotoxicity paper came out in 2007 that was among the papers triggering new concerns in Europe over formulated Roundup products. It was entitled "Cytotoxicty of the herbicide glyphosate in human peripheral blood mononuclear cells (Martinez A, Reyes I, Reyes N. (2007), *Biomedica* 27(4):594-604). The results and conclusions sections from the abstract of the paper follow:

*RESULTS:*
Both technical grade glyphosate and Roundup formulation were toxic to human peripheral blood mononuclear cells. Cytotoxicity of Roundup was higher than cytotoxicity of glyphosate, since the LC50 (50% lethal concentration) determined by the trypan blue exclusion method at 24 h was the equivalent of 56.4 microg/ml of glyphosate in the form of Roundup and 1,640 microg/ml (1.64 mg/ml) for technical grade glyphosate.

*CONCLUSIONS:*
This in vitro study confirmed the toxic effects on human cells by glyphosate and its commercial preparations. Commercial formulations were more cytotoxic than the active component alone, supporting the concept that additives in commercial formulations play a role in the toxicity attributed to glyphosate-based herbicides.

425. The 2007 Martinez et al study quoted above reports that the formulated Roundup product was 29-times more cytotoxic than pure glyphosate, a substantial difference with possible regulatory consequences.

426. Plans and initiatives inside Monsanto to deal with BfR regulatory concerns were a focus of a "Glyphosate Toxicology Peer Review" meeting held in London on June 22, 2007. Three senior, corporate Monsanto scientists were present (Donna Farmer, [redacted], [redacted]), and a fourth participated via the phone (Christophe Gustin). The Third-Party Network experts in attendance were Professor[redacted], Dr. [redacted], and Dr. [redacted]. [redacted] is listed as "Consultant." (MONGLY0118777).

427. One section of the meeting overview document is entitled "NOTES TAKEN DURING THE PRESENTATIONS." It includes sections addressing the issues facing Monsanto in preserving its glyphosate-related Freedom to Operate ("FTO") in Europe: carcinogenicity, endocrine disruption, co-formulants, and operator exposure.

428. Under "**4. Operator exposure**," there is a section setting forth "**Proposals for Action**." The first bulleted item reads: "Label recommendations for hand held spraying should include recommendation for using shields and not walking through the spray or sprayed area.

**ACTION: [redacted].**" "[redacted]" stands for [redacted], who was head of Regulatory Affairs for Monsanto in Europe. [redacted] was the individual responsible for submitting new or revised glyphosate-based herbicide label directions, including worker-safety requirements, to regulatory authorities. (MONGLY0118777).

429. Recall that the 1986 glyphosate Registration Standard document issued by the EPA included a requirement for goggles or a face shield, a requirement ignored by Monsanto regulatory officials in the U.S.

430. In my opinion, the recognition by Monsanto scientists and regulators in Europe of the need to require face shields in the case of hand held spraying was justified, and indeed overdue. The refusal of U.S.-based Monsanto officials to add a requirement for face shields or goggles onto Roundup-brand herbicides sold in the U.S. is further evidence that the company places little weight on its pledge to product safety.

## VIII. Monsanto Terminates TNO Study, Which Showed Elevated Rates of Dermal Absorption

431. Monsanto commissioned new studies on the rate of dermal penetration of Roundup herbicides, in response to questions from EU regulators. Studies responsive to this request were needed to sharpen estimates of worker-exposures and risk, especially in the case of formulated Roundup products containing POEA.

432. Monsanto commissioned a dermal penetration study in rats. It was conducted by a Denmark contract laboratory, TNO, in 2002.

433. The rate of dermal absorption when a person's skin is exposed to a glyphosate-based herbicide like Roundup is a key variable in estimating applicator exposure and risk. Low dermal-absorption rates, other things being equal, will result in less worrisome warning symbols on labels, less strict limits on use, and/or fewer and less onerous requirements for personal protective clothing and equipment for those mixing, loading, or applying pesticides.

434. In EPA's 1986 glyphosate Registration Standard and the 1993 EPA Re-registration Eligibility Document (RED), the agency incorporated an estimated 3% dermal penetration rate (also called an "absorption rate") for glyphosate in its estimates of applicator exposures and risk. This estimate, in turn, was based on studies conducted in the 1980s by Monsanto.

435. Monsanto was aware that EU regulators were asking for updated dermal penetration studies as part of the EU re-registration review of glyphosate. Hence, Monsanto's decision to contract with TNO to conduct a state-of-the-art rat skin penetration study.

436. An email exchange in April 2002 between Monsanto employees in Europe working on the new data required by German regulators, and senior Monsanto personnel in St. Louis (Heydens, Healy, Farmer, Martens, Wratten, among others), reported that Monsanto-

Europe had agreed to conduct a new *in vitro* dermal penetration study with rat skin.

437. The results of the TNO study were initially reported to a Monsanto scientist stationed in Belgium (Fabrice Broeckaert) via a phone call from TNO and were later transmitted in a 22-page "unaudited draft report" dated June 14, 2002 (MONGLY00888353-0088388). The "Draft report" stated that the dermal absorption rate for the glyphosate in the concentrate of the formulated Roundup herbicide (MON 35012) through rat skin is 10.3%, plus or minus 4.2%, resulting in a range of 6.1% to 14.5% after 48 hours of recovery.

438. TNO also tested the same MON 35012 formulation at a field-concentration rate that delivered a glyphosate dose of 0.08 $mg/cm^2$ during the experiment, as opposed to the 6.25 $mg/cm^2$ in the case of the concentrate (i.e., a 78-fold dilution rate). In the case of the field-diluted rate of MON 35012, the unaudited draft report reported that 2.6% +/- 1.4% of the glyphosate applied to the rat skin penetrated through it (range 1.2% to 4%).

439. TNO also measured rat skin penetration of pure glyphosate, MON 0139 70% solution (70% glyphosate, 30% water), both as a concentrate and diluted 79-fold. For the pure glyphosate concentrate, 1.3% +/- 1.9% penetrated the skin, and 1.4% +/- 2.2% in the case of the diluted, pure glyphosate test substance.

440. Based on these initial TNO study results, the percent of glyphosate penetrating the rat skin was 7.9-times higher in the case of the concentrate of the formulated product, compared to the concentrate of pure active ingredient.

441. According to Garnett, the large difference between the dermal absorption rate of formulated Roundup (mid-range estimate, 10.3%) compared to pure glyphosate (mid-range estimate, 1.3%), "confirm ***our expectation*** that surfactant concentration affects dermal absorption." (Emphasis added; MONGLY…)

442. In an April 2, 2002 email from William Heydens to his colleague Charles Healy about the "new issues and topics for the conf call of Tuesday, 2 April," Heydens wrote:

> "My primary concern is with glyphosate in terms of the potential for this [TNO] work to blow Roundup risk evaluations (getting a much higher dermal penetration than we've ever seen before." (Text as it appears in email; "[TNO]" is added).
>
> (MONGLY03738295).

443. An increase in the Roundup dermal absorption rate from 3% to around 10%, as seemingly called for in this TNO experiment, would increase estimated worker exposures and risks by about three-fold. Such results would undermine the risk assessments in existence at the time and would likely trigger a reassessment of worker risk levels and worker-safety requirements.

444. In an April 4, 2002, email, Broeckaert reports to the group that, as a result of the TNO results reported to Monsanto, "we came to the conclusion that the penetration of glyphosate would have been [probably] greater than the 3% already imposed by the German authorities. We decided thus to **STOP** the study (effective today)." (Emphasis in original; MONGLY03737015).

445. Donna Farmer replied to this email later the same day, asking for clarification, leading to an email the next day from Garnett, one of the Monsanto scientists directly involved with the scope and focus of recent and ongoing work on dermal absorption.

446. Garnett wrote in his April 5, 2002 email response to Farmer, and all others on the April 2 email chain, "We dropped the programme for glyphosate because a further study was not likely to help us meet the project objective".

447. In addition to stopping further studies Monsanto had planned to carry out at TNO, Monsanto scientists raised a number of questions and concerns about the TNO study. Issues involving the mass balance calculations were discussed, and addressed in a revised TNO report

dated November 14, 2002, and then again in another draft report dated April 9, 2013, and another dated March 27, 2003. The final report was dated July 23, 2003.

448. In each of the subsequent drafts, there was one significant change in the core results -- the percentage of the glyphosate penetrating the rat skin in the study testing the pure glyphosate concentrate fell to 0.52%, down from 1.3% in the initial draft report. As a result of this change, 20-times more glyphosate in the formulated product concentrate penetrated the rat skin, compared to the pure glyphosate product.

449. The July 29, 2003 final report states that because of "poor recoveries combined with the high variation within the glyphosate test groups make the data generated in this study unsuitable for risk assessment." (MONGLY01285831). This statement did not appear in the June 14, 2002 version of the TNO report.

450. In order to resolve any methodological issues in its rat skin penetration study conducted for Monsanto, TNO offered to repeat the study at no charge to the company. Monsanto did not take TNO up on its offer.

451. In my opinion, the core findings of the TNO study should have triggered additional studies, and at a minimum, Monsanto should have accepted the no-cost, repeat study offered by TNO. In addition, I conclude that the results in the initial TNO report dated June 14, 2002 should have been provided to the EPA in accord with FIFRA section 6(a)2(B). This provision in FIFRA requires that new, adverse data on a pesticide in the possession of registrants must be reported to the EPA within 90 days, including data in preliminary reports.

## IX. Monsanto's Relationships with "Friendly" Scientists and Officials in EPA

### A. Jess Rowland

452. Jess Rowland was the Deputy Director of the OPP Health Effects Division. He was directly involved in managing the EPA's internal assessment of glyphosate's oncogenicity, as well as the EPA's interactions with and response to the IARC review of glyphosate. He also served as a point of contact between EPA and other federal agencies, and managed CARC (Cancer Assessment Review Committee), a key, internal OPP committee that rendered judgement of whether a given pesticide poses cancer risk.

453. In a 2/20/15 email, as Monsanto was preparing for the release of the IARC report on glyphosate, William Heydens wrote an email to Dan Jenkins, his Monsanto colleague that worked most closely with EPA on registration issues at the time. The topic is "EPA Folks going to IARC" (i.e., attending the final IARC Working Group meeting in Lyons, France March 10-14, 2015).

454. Heydens reports on the two EPA scientists that "will actually participate in the meeting," and two other EPA representatives that will be attending as observers. He identifies the two observers as "Catherine [Eiden] is a Special Assistant in the Pesticide Re-evaluation Division, and we all know Jess." (MONGLY00986901).

455. In an April 27, 2015 email exchange between Dan Jenkins (registration, EPA interface) and William Heydens (toxicology, safety), Heydens asks Jenkins about approaching EPA and asking them directly "about what area they see as most problematic [in the IARC monograph] or just ask if there is anything that would help them [EPA] defend the situation?"

456. Jenkins responds: "I think you and I could get on the phone w Jess Rowland and discuss this openly. He'll give us straight talk." (MONGLY03929023).

457. The next day (April 28th), Jess Rowland called Dan Jenkins "out of the blue" and told Jenkins:

> "We have enough to sustain our conclusions [that glyphosate is not oncogenic]. Don't need gene tox or epi. The only thing is the cheminova [another registrant of glyphosate herbicides] study with the sarcoma in mice – we have that study now and its conclusions are irrelevant…I am chair of the CARC and my folks are running this process for glyphosate in reg review."
>
> (MONGLY00987756)

458. But Rowland had another message to pass on to Jenkins that day. The Agency for Toxic Substances and Disease Registry ("ATSDR"), another U.S. government agency responsible for assessing the toxicity of chemicals, was planning to undertake a review of glyphosate. According to one Monsanto scientist, ATSDR historically reached conclusions similar to IARC. An ATSDR determination similar to IARC's would raise doubts about the EPA's position that glyphosate does not pose cancer risk.

459. In this email, Rowland then asks Jenkins for a contact name at ATSDR, and reports that there is no coordination underway between EPA and ATSDR in terms of ATSDR's pending assessment of glyphosate. Then, according to Jenkins's email, Rowland said: "If I can kill this [the ATSDR review] I should get a medal."

460. In a September 3, 2015 email to a large group of colleagues, Dan Jenkins wrote that:

> "No questions but Jess Rowland at EPA is quite proud of their recent endocrine conclusions and is also on point regarding their IARC response. Jess will be retiring from EPA in ~5-6 mos and could be useful as we move forward with ongoing glyphosate defense."
> (MONGLY03351980)

461. Rowland was responsible for an October 2015 evaluation of glyphosate as head of the Cancer Assessment Review Committee (CARC). In conducting this review Rowland

apparently violated EPA's own cancer assessment guidelines in concluding that glyphosate was "Not Likely to be Carcinogenic to Humans." In a May 2, 2016 email, Jim Jones, an Assistant Administrator at the EPA, informed Gina McCarthy, the Administrator of the EPA that the CARC "assessment was not consistent with Agency's guidelines." (EELI_0000037).

462. The CARC Assessment was "inadvertently" released to the public, despite its violation of guidelines and "Monsanto saw it and put out a release saying EPA had confirmed glyphosate is not carcinogenic." (EELI_0000037).

463. The CARC assessment formed the basis of the OPP's September 2016 report on glyphosate oncogenicity. Considering Dr. Rowland relationship with Monsanto, it raises, in my opinion, serious questions about the objectivity of that report and the scientific basis of EPA's determination that glyphosate is "not likely" to pose cancer risk.

464. Other parts of the EPA have expressed skepticism about the conclusion reached by the OPP and CARC on the question of glyphosate's oncogenic potential. The Office of the Administrator in EPA was aware of the divergence in the EPA and IARC assessments and asked the agency's Office of Research and Development to share its views on OPP's glyphosate cancer risk assessment.

465. ORD prepared summary comments on OPP's classification in light of IARC's "probably carcinogenic to humans" determination. (EPA-HQ-2016-0140431_00000037-39). In point number 5, ORD addresses the importance of studies on the mutagenic (i.e., genotoxic) potential of glyphosate and GBHs. It notes that the EPA review of studies on glyphosate's mutagenic potential was not thorough. ORD then writes:

> "…if there is evidence of mutagenic potential or if a mutagenic potential has not been adequately ruled out, then the characterization of glyphosate as 'not likely to be carcinogenic' could be problematic for this reason alone, given the lack of a high-quality negative epidemiological study."

466. In my opinion, the IARC conclusion that there is "strong evidence" of GBH genotoxicity through at least two mechanisms known to be associated with human cancers more than satisfies the "evidence of mutagenic potential" referred to in the ORD memo.

**B. Jack Housenger**

467. As events unfolded in 2015 after the release of the IARC classification, the EPA's Office of Pesticide Programs still classified glyphosate as not likely to pose a human cancer risk. Moreover, EPA had been working for years on its own re-registration review of glyphosate. The key question was whether the IARC classification would alter EPA's judgement regarding glyphosate herbicide cancer risk.

468. At the time, Jack Housenger was the Director of the Office of Pesticide Programs and had been a senior OPP manager for many years.

469. The record (including text message exchanges) shows a close, deferential, and supportive relationship in communications from Housenger to Monsanto.

470. One example of Housenger taking the initiative to help Monsanto occurred in May, 2015, about two months after the release of the IARC report. Monsanto, Jess Rowland of EPA, and apparently Housenger raised concerns that a review of glyphosate toxicity by ATSDR might align with IARC's and undermine EPA's view.

471. After asking Monsanto for help identifying contacts at ATSDR, and calling the ATSDR staff member assigned to carry out the review, Housenger sent a May 20, 2015 email to Patrick Breysse, head of the ATSDR program. Housenger introduced himself as the Director of the EPA Office of Pesticide Programs (OPP), and updated him on the near-complete, comprehensive OPP review. Then he wrote:

"However, given that our reviews [OPP's and ATSDR's] would be basically done

> very close in time to one another, there is a question of whether this is a good use of government resources. I'd like to talk to you about this and can be reached at the number below." (Public document).

472. Breysse responds nine minutes later: "Can we discuss today or tomorrow". Housenger's email and call with Breysse, the ATSDR Director, was not the only contact he made with ATSDR. In an email sent June 24, 2015 to Dan Jenkins, Monsanto's senior D.C.-based registration official, Housenger writes:

> "Dan, here is everyone I talked to Henry [Abadin] was the one who ended up saying that they [ATSDR] would put glyphosate on hold holding the OPP risk assessment release [he actually meant "pending" rather than "holding" the OPP risk assessment release] Hope this helps Breysse, Patrick N…he's the Director of HCEH/ATSDR. Stephan, James W (aka Jimmy) he's the acting director of the Division of Community Health Investigation Henry Abadin…..he's the branch chief Hannah Pohl…..is the person doing the work on glyphosate"
>
> (MONGLY04028722).

473. On October 13, 2016, Jay Vroom of CropLife America (pesticide industry lobbying organization) called and emailed Jack Housenger to discuss removing epidemiologist Peter Infante from the glyphosate SAP panel, and to invite Housenger to a retreat with Monsanto and other industry executives at a West Virginia casino and resort. (EPA-HQ-2017-000442-0000205).

474. On October 14, 2016, the OPP announced that it was postponing the SAP hearing on glyphosate scheduled for October 18, 2016. On October 19, 2016, the OPP announced that Peter Infante would no longer be on the SAP panel evaluating glyphosate.

475. Jack Housenger attended a CropLife retreat at the Greenbrier Casino and Resort with executives of Monsanto and other pesticide companies in November of 2016, one month before a key SAP Panel hearing on glyphosate. These executives noted that, "[w]e had some quality time with EPA OPP Office Director Jack Housenger to dig into key issues and

operational matters at that vital department of EPA." (MONGLY07063555).

476. Like Rowland, Housenger's relationship with Monsanto and chemical industry raises serious questions about the objectivity and reliability of the OPP's recent assessment of glyphosate. Indeed, the SAP meeting convened to review the OPP's report agreed unanimously that the OPP did not follow the EPA guidelines in its review of the carcinogenicity of glyphosate. In my decades of experience reviewing OPP practices and EPA re-reregistration reviews, I have not become aware of a clearer example of regulatory capture.

## X. Monsanto Asks Dr. Parry to Assess Glyphosate Genotoxicity and Then Does Not Disclose His Findings to Regulators or Conduct the Studies He Recommends

477. In the 1990s several positive genotoxicity studies were published including:

- Lioi et al., (1998), Genotoxicity and oxidative stress induced by pesticide exposure in bovine lymphocyte cultures in vitro, *Mutation Research* 403: 13-20);
- Lioi et al., (1998), Cytogenic damage and induction of pro-oxidant state in human lymphocytes exposed in vitro to glyphosate, vinclozolin, atrazine, and DPX-E9636, *Environ. Mol. Mutagenesis* 32: 39-46);
- Bolognesi et al (1997), Genotoxic activity of glyphosate and its technical formulation Roundup, *J. Agric Food Chem* 45: 1957-1962); and
- Clements C, Ralph S, Petras M (1997), Genotoxicity of selected herbicides in *Rana catesbeiana* tadpoles using the alkaline single-cell gel DNA electrophoresis (comet). *Environ Mol Mutagen* 29:277–288.

478. The company decided to reach out to a well-known and respected expert in genotoxicity, Dr. James Parry, a professor in the School of Biological Sciences, University of Wales Swansea, in the UK.

479. To gauge how helpful Dr. Parry might be as a Third-Party Network member, and before committing to a more open-ended consulting agreement, Monsanto gave him a short-term assignment that entailed reviewing a set of then-recently published genotoxicity papers. A series of Monsanto emails were sent on May 16-18, 1999 discussing Parry's role, his fee (600 pounds a day), and estimated that the requested review would take about 10 days (total cost of 6,000 pounds). (MONGLY01825649).

480. In a letter dated August 18, 1999, Dr. Parry transmitted his first of three evaluation reports to Mark Martens, a Monsanto toxicologist. After reviewing a number of published, genotoxicity studies, along with the results of several of Monsanto's own studies, he offered 19 conclusions on the genotoxicity of glyphosate and formulated glyphosate-based herbicides.

481. Based on Dr. Parry's review: (1) six of his 19 conclusions were that certain types

of studies and assays showed no evidence of genotoxicity; (2) 6.5 studies/types of assays were positive for evidence of genotoxicity; and (3) 6.5 were equivocal and would need to be refined and/or repeated.

482. Parry then states: "I conclude that glyphosate is a potential clastogenic in vitro." He was unable to draw a conclusion on the clastogenicity of formulated glyphosate-based herbicides because of a lack of studies. He also states that "glyphosate mixtures [i.e. GBHs] may be capable of inducing oxidative damage in vivo."

483. Parry's two conclusions, reached in 1999, were similar to the primary reasons that the IARC classified the evidence on glyphosate's genotoxicity as "strong."

484. In addition to his written reports, Dr. Parry provided Monsanto with a detailed list of recommended research activities to clear up lingering questions over the genotoxicity of glyphosate-based herbicides, the mechanisms giving rise to genotoxicity, and relevance of these mechanisms to the evaluation of glyphosate's other health effects, and especially oncogenicity. (MONGLY01314264).

485. In his summary statement in the document setting forth research recommendations, Parry writes: "My overall view is that if the reported genotoxicity of glyphosate and glyphosate formulations can be shown to be due to the production of oxidative damage then a case could be made that any genetic damage would be thresholded. Such genetic damage would only be biologically relevant under conditions of compromised antioxidant status."

486. Two Monsanto scientists shared their reviews of the Parry report with colleagues. Stephen Wratten wrote an email entitled "Comments on Parry write-up" to Mark Martens and Donna Farmer. Wratten starts by saying: "I was somewhat disappointed…The style and rather

casual lack of completeness and preciseness would make it hard to circulate this around to anyone as supporting information."

487. Monsanto failed to provide the Parry Report to the EPA as required under 40 CFR § 159.158. FIFRA Section 6(a)2(B) spells out the adverse health effects information that must be submitted by registrants to the EPA:

> (a) General. Information which is reportable under this part must be submitted if the registrant possesses or receives the information, and the information is relevant to the assessment of the risks or benefits of one or more specific pesticide registrations currently or formerly held by the registrant. Information relevant to the assessment of the risks or benefits also includes conclusion(s) or opinion(s) rendered by a person who meets any of the following:
>
> (1) Who was employed or retained (directly or indirectly) by the registrant, and was likely to receive such information.
> (2) From whom the registrant requested the opinion(s) or conclusion(s) in question.
> (3) Who is a qualified expert as described in § 159.153(b).

488. In the next several days in early July 1999, Monsanto officials discuss internally whether to:

- Commission the new genotoxicity research studies Parry recommended;
- Ask someone else to interface with Parry to rough out the edges of his conclusions; or
- End the effort to cultivate Parry as a supporting expert.

489. The final decision came about two months later. In a September 16, 1999 email from Mark Martens to Heydens and Farmer, Martens asked for "your opinions and then have a discussion on the action to take?" (MONGLY03734971).

490. Heydens responds to Martens and Farmer later the same day, and writes:

> "However, let's step back and look at what we are really trying to achieve here. We want to find/develop someone who is comfortable with the genotox profile of glyphosate/Roundup and who can be influential with regulators and Scientific Outreach operations when gentox issues arise. My read is that Parry is not currently such a person, and it would take quite some time and $$$/studies to get him there. We simply aren't going to do the studies Parry suggests."

(MONGLY03734971).

491. Then, in this same email, Heydens states that Monsanto should accelerate the search for other genotoxicity experts who would be more "comfortable" with glyphosate's genotoxicity profile. The reason – "We have not made much progress and ***are currently very vulnerable in this area***. We have time to fix that, but only if we make this a big priority now." (Emphasis added)

492. For many months, Monsanto continued to discuss internally Parry's recommendations for more refined genotoxicity testing. There was a February 15, 2001 phone meeting in which Dr. Parry and two Monsanto scientists participated (Mark Martens and Richard Garnett). Internal reports and emails describe the meeting, which "started off in a tense atmosphere because Parry was irritated by the language used in the mutagenicity section of the Williams et al. paper." (2000 genotoxicity review, MONGLY02626553)

493. In a February 12, 2001 email from Mark Martens, a Monsanto toxicologist, to his colleagues Larry Kier, Donna Farmer, and William Heydens, Martens addresses Parry's recommendation to do additional *in vitro* micronucleus assays on Roundup surfactants. First, he says "let's include talk about laundry detergents, hand soap, dishwashing detergents…" that contain similar surfactant chemicals.

494. On the prospect of another company asking Monsanto for permission to test the genotoxicity of Roundup formulations, Martens says: "I know how I would react – with serious concern."

495. In explaining why he would be concerned, Martens lists five reasons or arguments that could be advanced to scientists or regulators. First, the surfactants in home cleaning products pose greater risk than ag products. Second, a positive study on a Roundup formulation might

trigger the notion that glyphosate might also be genotoxic. Third, pure glyphosate is not genotoxic, based on data generated mostly by Monsanto. Fourth, some tests on certain formulations and surfactants have been negative (with no mention of those reporting positive results).

496. His fifth reason is identified as a "fall back position":

> "…we can agree with some testing on either surfactant solutions (would suppliers agree with us?) or with ***glyphosate formulations which don't exist anymore on the market*** (e.g. MON 35050) [Roundup "classic"]." [Emphasis added).

497. Why would Martens acquiesce to the testing of a Roundup formulation no longer on the market, if the company's goal was to understand risk levels, and avoid exposing people now buying and spraying Roundup to levels possibly triggering adverse health outcomes?

498. In my opinion Dr. Parry's reports triggered an obligation to (1) report the information to the EPA; (2) update the Roundup label to disclose the potential of genotoxicity risk following significant and/or long-term exposures to Roundup; and (3) conduct the various studies proposed by Dr. Parry to explore the genotoxicity of formulated GBHs.

## XI. Corporate Ghost-Authorship/Writing

499. As used in this report, the term "ghost-authorship" and "ghost-writing" refer to three types of contributions to a written document by a person not listed as the author, or among the co-authors of a document: (1) producing the first and original draft of a document, or section(s) of a document; (2) revising a document, or its section(s), in a way that adds to or alters the substantive content of the document; and (3) providing information and text, either as original writing or text derived from an existing document, that is used by a listed author or co-author, or document editor, to alter the content of a document and/or respond to comments made during peer review.

500. Each of the above three types of ghost-writing are unethical and unacceptable in the scientific and regulatory communities.

501. As part of a stated intention to discredit the Seralini paper on the oncogenicity of GE corn and Roundup (see paras 803-833) and force its retraction, Monsanto and its network of third-party experts, including Dr. Bruce Chassy, referenced the Committee on Publication Ethics (COPE) "Ethical Guidelines for Peer Reviewers (Irene Hames on behalf of COPE Council, March 2013, v.1, www.publicationethics.org), and shared it with Wally Hayes, editor of *Food and Chemical Toxicology*, the journal that published the Seralini study.

502. The COPE guidelines include that authors and/or reviewers must "declare all potential conflicts of interest" and "recognize that impersonation of another individual during the review process is considered serious misconduct."

503. In multiple instances, Monsanto authors and reviewers failed to disclose obvious conflicts of interest in their interactions with journal editors. Multiple reviews of papers were submitted by one Monsanto scientist that were ghost-written, in whole or part, by others

"impersonating" the reviewer-of-record.

504. A 2005 editorial entitled "Ghost Writing Initiated by Commercial Interests" appeared in the *Journal of General Internal Medicine* (Vol. 20:549). It begins by saying:

> "The integrity of the published record of scientific research depends not only on the validity of the science but also on honesty in authorship…The scientific record is distorted if the primary purpose of an article is to persuade readers in favor a special interest, rather than to inform and educate, and this purpose is concealed."

**A. Gary Williams et al 2000 Paper**

505. In 2000, the peer-reviewed journal *Regulatory Toxicology and Pharmacology* published a paper entitled "Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient Glyphosate, for Humans" (Williams, GM, Kroes, R, Munroe, AC, Volume 3, pages 117-165).

506. In a PowerPoint presentation done on December 10, 2010 by David Saltmiras, a Monsanto toxicologist, this Williams et al (2000) paper was called "an invaluable asset" for "Monsanto responses to agencies…Scientific affairs rebuttals…Regulatory reviews." Later in the same slide, Saltmiras states that "More current external expert publications are now needed to support our FTO and Registration Reviews," and poses a question that had come up before in Gingerich's speculation about an EPA Scientific Advisory Panel meeting: "Will weight of evidence be measured by number of publications or quality of the science??" (MONGLY02067858)

507. The Williams et al (2000) paper emerged from a Monsanto commissioned and paid for project undertaken by the consulting firm then known as Intertek Cantox (http://www.intertek.com/scientific-regulatory-consultancy/).

508. With funding from Monsanto, Cantox commissioned and paid for Dr. Williams

and Dr. Kroes to write a review of the human safety of glyphosate and Roundup herbicides, and a Cantox employee Dr. Ian Monroe served as a third, listed co-author.

509. Dr. Gary Williams was a professor in the Department of Pathology, New York medical Center, Valhalla, New York. He had been a consultant to Monsanto in the past.

510. Dr. Robert Kroes worked for ROTOX, University of Utrecht, The Netherlands, and had worked with several Monsanto scientists stationed in Europe.

511. Dr. Ian Munro was an employee of Cantox Health Sciences International, the consulting firm hired by Monsanto to produce several peer-reviewed journal articles on glyphosate-based herbicides, in addition to Williams et al. (2000).

512. The Williams et al. (2000) paper is unusual in its scope and detail. It covers 48 pages in the journal and strives to accomplish two goals. First, it provides a summary of a significant portion of the toxicology test results from Monsanto-commissioned studies done to fulfill regulatory data requirements. In short, it restates Monsanto's findings and conclusions from company-commissioned regulatory studies.

513. Second, the paper discusses scientific findings relevant to the risk characterization and risk assessment of exposures to glyphosate and glyphosate-based herbicides. It directs special focus on papers in the peer-reviewed literature that the company regarded as inconsistent with its conclusions with respect to glyphosate oncogenicity and/or the genotoxicity of formulated glyphosate-based herbicides.

514. The paper's "Purpose and Scope" section states:

> "Certain sectors of the scientific and nonscientific communities have commented on the safety and benefits of pesticide use. With this in mind, parts of this assessment address specific concerns that have been raised by special interest groups. This review will focus on technical glyphosate acid; its major breakdown product aminomethylphisphonic acid (AMPA); its Roundup formulations; and the polyethoxylated tallow amine surfactant (POEA)."

515. There is no financial disclosure statement in the paper.

516. To determine if a financial disclosure statement had been added, the journal's website was visited November 25, 2017, and a search was conducted for the Williams et al paper. The search results were to this link:

http://www.sciencedirect.com/science/article/pii/S0273230099913715

517. The paper is now available for online purchase. The abstract is available for no charge, and lists the three authors and their affiliations, but no information is offered on who paid for the study, or the substantial role of Monsanto in writing the paper.

518. The paper's Acknowledgement statement reads in full:

> "The authors acknowledge the assistance of individuals who participated in the preparation of this document. First, we are grateful to those who gathered and made available the large amount of information used to write the manuscript for this document. Second, we thank the toxicologists and other scientists at Monsanto who made significant contributions to the development of exposure assessments and through many other discussions. The authors were given complete access to toxicological information contained in the great number of laboratory studies and archival material at Monsanto in St. Louis, Missouri, and elsewhere. Key personnel at Monsanto who provided scientific support were William F. Heydens, Donna R. Farmer, Marian S. Bleeke, Stephen J. Wratten, and Katherine H. Carr. We also acknowledge the participation and assistance of Douglass W. Bryant and Cantox Health Sciences International for scientific and logistical support in the preparation of the final manuscript."

519. The second point in the Acknowledgment statement credits "toxicologists and other scientists at Monsanto who made significant contributions to the development of exposure assessments and through many other discussions."

520. "Significant contributions to the development of exposure assessments" refers to methodological and/or data and statistical work done by Monsanto on exposure assessment, but does not encompass ghost-writing of the sections of the paper on exposure assessment.

521. The acknowledgement that Monsanto toxicologists and other scientists "made

significant contributions through…many other discussions" does not disclose, nor even hint at ghost-writing.

522. On the role of five "key personnel" at Monsanto, the authors state that their participation and assistance entailed "scientific support," a phrase that means Monsanto provided access to data, analytical tools or models, or other scientific information generated by Monsanto.

523. In my opinion, this Acknowledgement statement is false, incomplete, and misleading, because it fails to disclose the multiple, substantial instances of substantial authorship contribution made by Monsanto employees to the paper as published.

524. William Heydens states in a 2015 email that "we", i.e., Monsanto, ghostwrote Williams (2000), in the context of discussing plans to ghostwrite an updated publication in 2015. Heydens proposes that, for the new paper, "...we ghost-write the Exposure Tox & Genetox sections...we would be keeping the cost down by us doing the writing and they would just edit & sign their names so to speak. Recall that is how we handled Williams Kroes & Munro, 2000." (MONGLY00977264).

525. In addition to Dr. Heydens admitting that he and other Monsanto scientists ghostwrote the article, Monsanto also documented the writing process for the Williams et al paper, showing that Heydens was largely responsible for drafting the manuscript. (MONGLY02598454).

526. Heydens' efforts were extensive, as he noted "I have sprouted several new gray hairs during the writing of this thing..." (MONGLY0186926).

527. On June 18, 1999, Douglas Bryant, a Cantox employee, sent a "progress report" on "Roundup documents [papers in preparation by Cantox]" in an email to his client and principle Monsanto contact, Lisa Drake. He copied two people: (1) William Heydens, the senior

Monsanto corporate official overseeing the Cantox project and similar "science outreach" efforts, and (2) Cantox colleague and paper co-author Ian Munro.

528. On the subject of the Williams et al. (2000) paper on glyphosate health effects, Bryant reports on the status of various reviews, including one by co-authors Kroes and Dick Peterson. He writes: "Bill Heydens, Donna Farmer, Kathy Carr and all those at Monsanto have been helping get the document through QA."

529. If doing so simply entailed catching and fixing errors, such input would be consistent with the acknowledged role played by Monsanto scientists and toxicologists.

530. Bryant then outlines the final steps in the process prior to submission of the paper to the journal: Bill Heydens completes the QA changes; sends edited and corrected version back to Cantox to incorporate final comments by the internal-to-Monsanto and Cantox reviewers (e.g. Peterson), and then the paper will be sent to the journal.

531. Twenty-seven minutes after the Bryant email was sent, Heydens sent this reply to Bryant and the other recipients of the original email. It was addressed to "All," and states:

> "A clarification – there is one step missing – I will review the final manuscript with the reviewers comments incorporated (in revision mode so I can find them easily) before it is sent to the publisher. I will commit to conducting this review very quickly. Assuming the reviewers don't throw any surprises (I'm especially thinking of Peterson), I can turn this back around with a very minimal investment of time."

532. Three days later, on June 21, 1999, Heydens sends a two-line email to his colleague Donna Farmer, where he states "And Dougie [referring to Bryant] thinks I would actually leave the final editing to him unsupervised…" This control over the final submission of the publication to the journal was never disclosed in the final publication acknowledgment.

533. By September 15th, nearly-three months after the June 18, 1999 Bryant email exchange, there had been multiple calls, exchanges of written material, and meetings between

Bryant and Cantox, and Monsanto regarding the content and finalization of the Williams et al (2000) paper. (MONGLY00905085).

534. The September 15th email from Bryant to Heydens copies Lisa Drake and Katherine Carr of Monsanto, but not any of the co-authors. It states that: (1) Bryant is sending a revised draft of the paper to the three co-authors Williams, Kroes, and Munro today; (2) the draft manuscript includes "all the changes that were discussed today and during calls last week. Please check it over to be sure that I have been thorough"; each co-author is asked "to complete his review and respond so journal submission (*Food and Chemical Toxicology*) can be finalized for September 30, 1999"; and, thanks everyone "for all your effort (undoubtedly there will be more)…"

535. Later that same day, September 15, 1999, Heydens sends another short, cryptic email to Donna Farmer and Stephen Wratten. This time he writes (exactly as in email): "FYI – in case you want to see how it ended up (hopefully, that is! – I'll strangle Kroes or Williams if they ask for any re-writes!!) Bill." By "it," Heydens is referring to the pre-submission draft of the Williams et al paper.

536. A submission of this paper to a peer-reviewed journal consistent with COPE guidelines would have listed several senior Monsanto scientists as the co-authors.

537. It is not clear in the record whether Munro made any substantive contributions to the paper. In a July 30, 1999 email from Heydens to Munro, Heydens writes: "Everyone at Monsanto has agreed with adding you as an author – please do so." (MONGLY01869261)

**B. Williams et al 2012**

538. In 2012, Monsanto commissioned another team to produce an updated review of recent studies assessing the differential cellular toxicity of glyphosate and formulated Roundup

herbicides. This paper appeared in the *Journal of Toxicology and Environmental Health, Part B Critical Reviews* (15(1): pages 39-96). The lead author was AL Williams (not Gary Williams), and RE Watson and JM DeSesso were listed as co-authors.

539. Monsanto employee Donna Farmer made significant contributions to the manuscript but was not listed as a co-author. In an email sending one round of her work on the manuscript to DeSesso, Farmer states, "[a]ttached is the first 46 pages. I added a section in genotox from the Gasnier study ...see attached a critique we did that I took that from. Am working on a section for Gasnier in the mechanistic section. Also we cut and pasted in summaries of the POEA surfactant studies. Attached are more detailed summaries - see Knapp." (MONGLY00919381)

540. In the draft manuscript attached to the email Donna Farmer's name is edited out as a co-author. (MONGLY00919400)

**Developmental and Reproductive Outcomes in Humans and Animals after Glyphosate Exposure:**
**A Critical Analysis ~~of the Available Literature~~**

Amy Lavin Williams[1, 2]
Rebecca E. Watson[1, 3]
~~Donna R. Farmer~~[4]
John M. DeSesso[1, 2, 5~~4~~]

541. The co-authors conducted a detailed review of dozens of studies, and concluded:

> "An evaluation of this database found no consistent effects of glyphosate exposure on reproductive health or the developing offspring. Furthermore, no plausible mechanisms of action for such effects were elucidated. Although toxicity was observed in studies that used glyphosate-based formulations, the data strongly suggest that such effects were due to surfactants present in the formulations and not the direct result of glyphosate exposure."

542. The 2012 review was critical of a set of five genotoxicity studies carried out by a team of French scientist led by Dr. R. Belle.

543. In an effort to explain the substantial difference in the conclusions expressed by Williams et al. (2012), in contrast to several published studies, a Letter to the Editor by Belle et al. (2012), "Toxicity of Roundup and Glyphosate," Vol 15: pages 233-237) states:

> "The authors [of Williams et al (2012)] do not take into account in their interpretation of our results the ***very poor cell membrane permeability of pure glyphosate***."
>
> (Emphasis added).

544. In concluding their letter, Belle et al. write:

> "Although we notice that Monsanto, the manufacturer of Roundup, financed their work, we would have expected strong scientific arguments against our results or alternative findings that would evidence the contrary. This is not the case, and, to our knowledge, our experiments, first published in 2002 and brought to Monsanto's knowledge as early as 1999, have not been demonstrated to be incorrect or biased."

545. In my opinion, Dr. Farmer played a substantial role in preparing the final publication and should have been listed as an author. By concealing her involvement with the publication, a scientist or researcher would not be aware that the publication was authored, in part, by an employee of the manufacturer of the product being discussed.

### C. Kier and Kirkland 2013 Paper

546. In 2013, the journal *Critical Reviews in Toxicology* published a peer-reviewed paper entitled "Review of genotoxicity studies of glyphosate and glyphosate-based formulations" (Vol 43(4)). Two authors were listed -- Monsanto consultant and former employee, Larry Kier, and Dr. David Kirkland, a professor and Monsanto consultant.

547. The abstract of the 2013 paper reports that it updates an earlier review of studies on the genotoxicity of glyphosate and formulated glyphosate-based herbicides. This earlier review was the Monsanto commissioned and ghost-written paper Williams et al. (2000) discussed earlier.

548. The "Monsanto Manuscript Clearance Form" for the 2013 Kier-Kirkland publication is dated 2/29/2012, and lists two authors: "David Saltmiras, Larry Kier (consultant)." Under "Lead Author's Comments," Saltmiras (presumably) writes: "This work falls under the scope of the EU Glyphosate Task Force and will be a valuable resource in future product defense against claims that glyphosate is mutagenic or genotoxic." (MONGLY02117600)

549. When published, the authors are listed as Kier and Kirkland. Saltmiras' name is deleted. Accordingly, the 2013 genotoxicity review paper is a ghost-written update of a ghost-written 2000 review.

550. In the published version of the Kier-Kirkland 2013 paper, the "Declaration of Interest" states:

> "Larry Kier and David Kirkland were paid consultants of the Glyphosate Task Force for the preparation of this review. The Glyphosate Task Force is a consortium of 25 European glyphosate registrants, listed on http://www.glyphosatetask-force.org/. Larry Kier is also a past employee of Monsanto Company. Monsanto Company was the original producer and marketer of glyphosate formulations. The authors had sole responsibility for the writing and content of the paper and the interpretations and opinions expressed in the paper are those of the authors and may not necessarily be those of the member companies of the Glyphosate Task Force."

551. This "Declaration of Interest" is only partially truthful. Kier and Kirkland did not write the paper alone; a third author, David Saltmiras, had contributed substantially to the paper, but is not listed as a co-author (his help is noted in the Acknowledgements).

In internal emails, dated January 2013, Saltmiras specifically requests his inclusion as a named author, but Kirkland rejects this request, explaining "As much as I agree with recognising the effort David S has put in, I do not think you can start adding an author at this stage. Apart from anything else, it means the authors would no longer be 'independent'." (MONGLY04086537). Thus, despite Saltmiras' contributions to article, his name was not list an

author. Indeed, even Kier acknowledges, "David S. was a co--author on the unpublished literature review manuscript which was the first phase of this project which I think qualifies him as a valid contributor to the manuscript."

552. In my opinion, the authors did not have sole responsibility for the content, and Monsanto, through its consultants Kier and Kirkland, and employee Saltmiras, was largely responsible for the content, not the Glyphosate Task Force. (MONGLY02145924-30). In my opinion, Saltmiras' contributions qualified for authorship and the failure to disclose his involvement is contrary to academic and scientific standards.

### D. *Critical Reviews of Toxicology* Special Issue on Glyphosate Risks

553. One of the clearest examples of ghost-writing in this case is the special issue put out by *Critical Reviews of Toxicology* (*CRT*). This special issue was conceived and commissioned by Monsanto when the company learned that the International Agency for Research on Cancer (IARC) would soon issue a monograph discussing the potential of glyphosate-based herbicides to cause cancer.

554. These series of articles was discussed in a response to IARC, when Heydens writes in an email with the subject "IARC Planning" that:

> If we went full-•bore, involving experts from all the major areas (Epi, Tox, Genetox, MOA, Exposure - not sure who we'd get), we could be pushing $250K or maybe even more. A less expensive/more palatable approach might be to involve experts only for the areas of contention, epidemiology and possibly MOA (depending on what comes out of the IARC meeting), and ***we ghost-write the Exposure Tox & Genetox sections***. An option would be to add Creim and Kier or Kirkland to have their names on the publication, but we would be keeping the cost down by us doing the writing and they would just edit & sign their names so to speak.
>
> (Emphasis added, MONGLY02078590).

555. In another planning document titled, "Proposal for Post-IARC Meeting Scientific

Projects" it posits the creation of a "Publication on Animal Carcinogenicity Data" where it openly states, "Majority of writing can be done by Monsanto, keeping OS$ down." (MONGLY01228576).

556. In another email, dated May 11, 2015, Michael Koch (Dr. Farmer's boss and head of product safety within Monsanto), notes that Monsanto will attempt to get a "Publication on Animal Data Cited by IARC" and that the "Manuscript to be initiated by MON as ghost writers." (MONGLY01023968).

557. The contents of this entire special issue of *CRT* was a Monsanto-controlled, and largely Monsanto-written rebuttal of the evidence cited by IARC in support of its "probably carcinogenic to humans" classification. Each paper had a mix of consultants and "independent" scientists listed as co-authors, but failed to disclose various Monsanto scientists who had made substantive contributions to the papers, including drafting full sections, if not full first drafts.

558. There are dozens of emails and other documents in the record memorializing the role Monsanto played in the conceptualization, writing, revisions, and publication of the papers in the special issue of *CRT*. For example: MONGLY00978170, MONGLY00992949, MONGLY00994301, MONGLY00998682, MONGLY00999487, MONGLY01000676, MONGLY01023968, MONGLY011300799, MONGLY01183933, MONGLY01228589, MONGLY02085862, MONGLY02133654, MONGLY00998684 and MONGLY02359008. Many of the communications are between Monsanto scientists and individuals working for the Canadian consulting firm Intertek. This firm was hired by Monsanto to manage the process of producing the papers that would appear in the special issue of *CRT*.

559. The consulting firm Intertek is basically the same company that Monsanto hired in 1998 to manage the process of putting together the also-ghost-written Williams et al (2000)

review of glyphosate toxicity. Back then, the consulting firm's name was CanTox Intertek.

560. Intertek served as the primary mechanism through which ghost-written material from Monsanto was incorporated in the drafts of the papers that were subsequently reviewed, edited, augmented, and approved by the listed, Monsanto and non-Monsanto co-authors.

561. In addition, Intertek also served as the primary point of contact with the editor of the journal *CRT*. This arrangement shielded the journal's editor from evidence of Monsanto's direct role, not just as a ghost-writer of parts of some of the papers, but as the primary author of several of them, and an important contributor to all of them.

562. In MONGLY00998682 transmits William Heydens edits on the "Summary Report" paper for the *CRT* special issue back to Ashley Roberts, Senior VP of the Food and Nutrition Group at Intertek. Roberts served as the principle point of contact between Monsanto and Intertek, and between Intertek and paper co-authors.

563. Throughout the review process, Roberts also was the primary point of contact between the paper co-authors and the journal *CRT*. A clear example arose in the wake of the efforts by Monsanto to produce peer-reviewed papers and make presentations at scientific meetings critical of the IARC Working Group's classification of glyphosate as Group 2A, "probably carcinogenic to humans."

564. William Heydens was organizing a group of Monsanto third-part experts and consultants for the "Expert Panel Review of the Carcinogenic Potential of the Herbicide Glyphosate," to be held at the 2015 Society for Risk Assessment (SRA) Annual Meeting. (MONGLY01030787).

565. Via a November 3, 2015 email, he circulated the panel makeup to John Acquavella and Larry Kier, individuals who had been involved in writing, and/or ghost-writing

the papers published in the special glyphosate issue of *Critical Reviews of Toxicology* published in 2016.

566. John Acquavella replied about an hour later that his name should be in the co-author list, to which Heydens replies: "I thought we discussed previously that…we would not be able to use you or Larry as Panelists/authors because of your prior employment at Monsanto."

567. Just over an hour later, Acquavella responds to Heydens: "I didn't realize that Bill. Also, I don't think that will be okay with my panelists. We call that ghost writing and it is unethical." (MONGLY01030787).

568. Heydens replied to Acquavella, writing: "We will have to pick this up tomorrow." The next day at 9:25 a.m., Heyden emails Acquavella, copying Donna Farmer, the Monsanto scientist managing Acquavella's consulting work. Heydens proposed a call later in the day. Acquavella responds and sets the time for the call. And then he adds:

> "You guys know me. I can't be a part of deceptive authorship on a presentation or publication. Please note the ICME guidelines below [which he attached to his email] that everyone goes by to determine what is honest/ethical regarding authorship."

(MONGLY01030787).

569. On September 26, 2018, the CRT issued an Expression of Concern regarding these panel manuscripts. In it, the publisher expressed "concerns over the completeness of acknowledged contributions to the above supplement" and explained "[w]e have not received an adequate explanation as to why the necessary level of transparency was not met on first submission. We thank those who brought this matter to our attention. When reading the articles, we recommend that readers take this context into account. We will continue to work to update these articles and ensure full disclosure of all contributions to them."

570. Similarly, on the same day, three of the named authors on the manuscripts issued

Corrigendums, correcting their disclosures and revealing Monsanto's involvement more clearly. Although these documents are not accurate or complete, they are a step in the right direction. Each of these corrigendums specifically apologizes for their errors. When Farmer was recently questioned about this and, on behalf of Monsanto, refused to apologize for Monsanto's role in this.

571. In my opinion, the CRT articles did not properly disclose Monsanto's involvement in their publication and were not, purported in the publications, "independent" reviews. Monsanto's role in failing to reveal its involvement in their publication fell below the standard required of a pesticide manufacturer or any academic / scientific institution.

**E. Other Forms of Ghost-Writing**

572. The above cited examples of ghost-writing involve unattributed contributions to papers in peer-reviewed scientific journals with explicit conflict of interest and disclosure rules that clearly prohibit ghost-writing.

573. There are other examples of ghost-writing as well.

574. On August 19, 2008, Dr. Charles Healy, a senior Monsanto scientist, received an email request from the Editor of the journal *Cell Biology and Toxicology* to review a glyphosate genotoxicity paper entitled "Cytotoxicity of herbicide Roundup and its active ingredient, glyphosate in rats." (MONGLY02286842).

575. He accepted the assignment and contacted his Monsanto colleagues David Saltmiras and Donna Farmer later in the same day. He asked them to conduct the review, explaining:

> "You two would be the reviewers in fact and I would then collate your comments and be the reviewer of record."

576. In this circumstance, it would have been entirely routine for Healy to write back

to the Editor and ask for permission to conduct the review with assistance from two Monsanto colleagues who have deep expertise on the subject matter of the paper. The Editor would have almost certainly approved Healy's request, and thanked him in advance for taking on the assignment.

577. In my opinion, ghostwriting a peer review is unethical and poses significant risk to the scientific and academic process. The journal did not know that a Monsanto employee was actually reviewing the paper, critical of glyphosate, and thus was from someone with a serious conflict of interest.

578. The ghost-written Healy et al. review of the paper is nearly five pages, single-spaced, and is about the same length as the paper, when it was published about a year later. The Healy et al. review is brutal, rating the paper a 5 on a scale of 1 to 100 (100 top rating) and "unacceptable" for publication.

579. On September 9, 2008, an email from the journal is sent to Healy stating: "I have had completely opposite reviews on this paper. I would be very grateful for your comments before giving the authors a decision." Later the same day, Healy forwarded this message to Saltmiras and Farmer, and adds: "Looks like ours will be the deciding vote as to whether the glyphosate paper is published."

580. A little over a year later, a revised version of the paper reviewed by Healy et al. appeared in the journal *Environmental Toxicology and Pharmacology* (Vol 28:379-385). The author is Nahla S. El-Shenawy.

581. Rising concerns over Roundup's human health effects in Latin America led to a Monsanto-organized Toxicology Expert Panel meeting in October 2012. David Saltmiras was charged with putting together an invited, expert panel for the meeting. A seminar on the history

and activities of the EU Glyphosate Expert Advisory Panel was among the presentations Saltmiras was organizing.

582. In an August 13, 2012 email, Saltmiras shares with colleagues that he will invite Sir Colin Berry or Jack Mandel to present talks during the seminar and adds that "I will likely prepare the presentation and send to him to change/adapt as he sees fit."

583. David Saltmiras engaged in an email discussion on January 26, 2013 with Monsanto-consultant and former employee Larry Kier over whether Saltmiras should be added as a co-author of Kier and Kirkland (2013), since Saltmiras wrote a significant portion of the paper. Saltmiras tells Kier that he had been strongly encouraged by "Senior Monsanto management" to author peer-reviewed publications, and that this Kier and Kirkland paper "***is the fifth such Glyphosate related manuscript I have been involved with over the past few years without co-authorship***." (Emphasis added, MONGLY04086532).

584. In his 2012 performance evaluation, Saltmiras wrote "Successfully facilitated numerous third party expert letters to the editor which were subsequently published..." on the Seralini study. He also "accepted an invitation to be a peer-reviewer for a 'high profile' toxicology journal…peer reviewed several manuscript submissions, wherein my recommendations to reject those manuscripts were accepted/adopted by the Editor." (MONGLY101045300).

585. As part of his 2015 performance evaluation, Saltmiras summarized his glyphosate-related activities, which included "ghost wrote cancer review paper Greim et al. (2015), coord Kier (2015) update to K&K, pushed for Sorahan (2015)." (MONGLY017223742).

586. These numerous examples, in my opinion, reflect instances of conduct which run counter to the basic precepts of scientific integrity and transparency.

## XII. Responses to Scientists Raising Concerns over Glyphosate Safety

### A. IARC Working Group Members

587. Dr. Consolato Maria Segi, a professor at the University of Alberta, Canada, was a member of the IARC Working Group that carried out the assessment of the oncogenicity of glyphosate.

588. After the release of IARC Monograph 112 and announcement of the 2A "probably carcinogenic to humans" classification, Dr. Sergi received a letter dated October 31, 2016 from a U.S. based law firm, Hollingsworth LLP. This firm had been hired by Monsanto to carry out various activities in response to the IARC decision. Apparently, several other IARC Working Group members received a similar letter.

589. According to Dr. Sergi's response dated November 4, 2016, the law firm's letter requested "disclosure of files used in connection with the preparation of the IARC Monograph Volume 112." Prior to responding, she consulted with colleagues on the Working Group and IRAC.

590. She replied that the files belonged to IARC, and the result of their deliberations were explained in detail in the monograph. She then wrote:

> "I found your letter ***intimidating*** and ***noxious*** even though transparency is important…It is impolitic to mention possible consequences without identifying the correct background. I find your approach reprehensive and lacking of common courtesy even by today's standards. As a graduate of a British educational system, I consider your letter ***pernicious***, because it maliciously seeks to instill some anxiety and apprehension in an independent group of experts…Please avoid contacting me or any of my colleagues in the future regarding this issue."
>
> (Emphasis in original; Heydens Exhibit 3-54)

### B. Seralini Team

591. On September 19, 2012, a team of French scientists led by Gilles-Eric Seralini

published a paper entitled "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize" in the journal *Food and Chemical Toxicology* (Vol 50: 4221-4231).

592. The paper reported the results of a two-year rat study. Both formulated Roundup herbicide and GE-corn, fed separately and together, were found to trigger a variety of pathologies including cancer, damage to the pituitary gland, liver, and kidneys, and premature death.

593. The kidney emerged as a particularly vulnerable organ, given that 76% of the impacted parameters were associated with kidney deficiencies.

594. The abstract ends with this statement:

> "These results can be explained by the non-linear endocrine-disrupting effects of Roundup, but also by the overexpression of the transgene in the GMO and its metabolic consequences."

595. The Seralini study was the first, independent two-year rat feeding study designed to sort out the individual and combined impacts of long-term exposure to a GE corn (NK603) and formulated Roundup herbicide. Previously, Seralini and colleagues had conducted several genotoxicity experiments comparing the toxicity of glyphosate and formulated Roundup in cell assay systems.

596. The paper's findings received extensive media coverage in the U.S. and Europe, and posed a significant threat to Monsanto's commercial interests, as well as a major challenge for regulators who had previously approved both Roundup and GE, "Roundup Ready" corn.

597. The next day, September 20th, David Saltmiras sent an email to Sir Colin Barry and Andrew Cockburn, a consultant working for Monsanto. It marks the beginning of a campaign that would last years, with the goal of discrediting the Seralini paper and team.

598. In the email, Saltmiras calls the paper "junk science." He questions what

happened with the journal's peer review process, and states: "I also suspect this paper may be in our own best interests – the last rites for Seralini's few remaining shreds of scientific credibility." (MONGLY01096620).

599. In my opinion, regardless of the merits and faults of the paper, the rapidity and scope of negative commentary, beginning on the day the paper was released, was unprecedented.

600. A week after the paper's release, a Monsanto-funded, retired academic in the U.S., Dr. Bruce Chassy, emailed the journal editor Wallace Hayes calling for the paper to be retracted, in order to save the reputation of the journal. (MONGLY00900629).

601. After Hayes responds and says he will process Chassy's email as a letter to the editor, and give the Seralini team an opportunity to reply in accord with standard journal policy, Chassy quickly replies and writes that his initial email "was a heartfelt expression by a caring colleague who is deeply concerned…My intent was to urge you to roll back the clock, retract the paper, and restart the review process." Then, Chassy alleges that "The paper in question has not been peer reviewed," a claim which he no doubt knew was false.

602. In the coming weeks and months, Monsanto encouraged and orchestrated a series of critical commentaries, that included allegations of scientific fraud by the Seralini team.

603. A exchange of emails between senior Monsanto officials and scientists occurs on September 26, 2012. Saltmiras starts the email chain at 11:50 a.m., which is sent to seven colleagues, including Eric Sachs, Bill Heydens, Bruce Hammond, and Daniel Goldstein.

604. In the email, he reports on a call he had earlier that morning with the journal editor, Wallace (Wally) Hayes. Saltmiras writes:

> "He [Hayes] expressed concern that to date he has only received links to blogs, web postings, media releases, etc. and no formal letters to the Editor…Therefore, he urgently needs rational, objective and authoritative formal letters to the Editor….I believe he would like such letters TODAY!"

(Emphasis in original, MONGLY02063095-96)

605. Among "Actions" Saltmiras lists in his email, he reports that he has emailed the EU Glyphosate Task Force (GTF) Toxicology Working Group, suggesting that the GTF submit a letter; that Eric Sachs (Monsanto's head of Regulatory Policy & Scientific Affairs) will follow-up with "his third party scientific experts…and request they consider formal letters to the Editor." Last, Saltmiras asks for his colleague's "thoughts on promptly moving forward."

606. Eric Sachs responds 13 minutes later, reporting that Bruce Chassy will soon submit his letter to the journal, and "notify other scientists that have sent letters [to media outlets or Monsanto] to do the same. He understands the urgency."

607. Fifteen minutes later, Heydens replies to the group: "And I very strongly believe we must go ahead and put together a Monsanto letter to the editor…"

608. Four minutes after receipt of Heydens' email, Eric Sachs writes to the group: "I remain adamant that Monsanto must not be put in the position of providing the critical analysis that leads the editors to retract the paper." (MONGLY02063096).

609. Heydens replies privately to just Sachs a few minutes later:

> "This [Sachs' recommended role for Monsanto] makes no sense to me at all. We have defended our science every step of the way since our 1st encounter with him [Seralini]. That fact remains that the external sector has not given us what we need, and the editor is telling us it is the 11th hour…"

610. Sachs then replies just to Heydens:

> "I am not challenging that Monsanto should defend our science – we absolutely should and have. There is a difference between defending science and participating in a formal process to retract a publication that challenges the safety of our products. We should not provide ammunition for Seralini, GM critics and the media to charge that Monsanto used its might to get this paper retracted. The information we provided clearly establishes the deficiencies in the study as reported and makes a strong case that the paper should not have passed peer review. We have done our part. It is time now for the public sector and especially

our network of experts to do theirs."

(MONGLY02063095-96).

611. In this exchange, Sachs argues that Monsanto must not be perceived as orchestrating and supporting a campaign that is designed to force the journal to retract the Seralini paper, but that is essentially what they did, beginning with the sharing of Monsanto-written criticisms of the Seralini study, before its public release, to a number of its third-party experts who were quoted in various media stories, and/or wrote blogs, commentaries, and letters to the editor.

612. Two days later, in an email from Daniel Goldstein to Sachs on the effort to encourage letters to the editor, Goldstein writes to Sachs: "We are being asked to keep internal correspondence down on this subject." (MONGLY00936725).

613. In early October, Goldstein shared notes from conference calls with Monsanto scientists and registration specialists in multiple countries regarding the fallout from the Seralini study. It includes "A list of pending actions in St. Louis is provided below." (MONGLY00978885-90).

614. These actions and "Key Points" cover Monsanto efforts to support the retraction campaign; studies that Monsanto should consider undertaking to have a basis to challenge the findings in the Seralini paper; and, rebuttal arguments and related talking points to share with regulators trying to encourage retraction of the Seralini paper.

615. Then Goldstein writes: "c. And finally – the one [new study that Monsanto should consider doing] you have all been waiting for: ***2 year rat/chronic studies of pesticide formulations on crop."*** (Emphasis added).

616. The Monsanto letter to the Editor of *Food and Chemical Toxicology* appeared in

March 2013 (Hammond et al Vol 53: 459-464). It spanned six pages of text in the journal; the original Seralini paper was 11 pages, of which about 4.5 pages were tables, figures, and photos. The Monsanto letter was signed by three Monsanto scientists: Bruce Hammond, Daniel Goldstein, and David Saltmiras.

617. Remarkably, the authors of the letter write "The authors declare that there are no conflicts of interest" in the section of the letter labeled "Conflict of Interest," when in fact it is hard to imagine how three co-authors could be more directly or fully conflicted.

618. On November 19, 2013, *Food and Chemical Toxicology* Editor Wallace Hayes wrote Seralini a letter informing him that his paper would be retracted. The letter included the retraction statement that Hayes was going to publish. It recounts the controversy, the letters to the editor, "and even allegations of fraud."

619. At the time that Wallace Hayes decided to retract the paper, he had been hired to be a paid consultant for Monsanto at $400 per hour. (MONGLY02185742). This information was never disclosed during this time where Seralini's credibility as a scientist was under assault or to the readership of the journal.

620. Then, Hayes writes: "Unequivocally, the Editor-in-Chief found no evidence of fraud or intentional misrepresentation of the data…Ultimately, the results presented (while not incorrect) are inconclusive, and therefore do not reach the threshold of publication in *Food and Chemical Toxicology*."

621. In my opinion, the retraction of a scientific paper for reporting inconclusive results is extremely rare, and if such a test for conclusiveness of results were adhered to consistently by journal editor, the number of published papers would be dramatically reduced. It is also my opinion that Monsanto's financial relationship with Hayes should have been disclosed.

This amounted to a serious conflict of interest.

### C. The IARC Classification

622. The International Agency for Research on Cancer (IARC) released a summary of its Working Group report on glyphosate and glyphosate-based herbicides via a short report published in the May 2015 issue of *The Lancet Oncology*, a highly regarded medical journal. The full Working Group monograph was initially published on July 29, 2015, and a lightly revised version was released January 26, 2017 in which some references and typos were corrected (http://monographs.iarc.fr/ENG/Monographs/vol112/mono112.pdf).

623. The concluding section of the full monograph discussing the basis for the Working Group's classification decision states:

> **"6.3 Overall evaluation**
>
> Glyphosate is *probably carcinogenic to humans (Group 2A).*
>
> 6.4 Rationale
>
> In making this overall evaluation, the Working Group noted that the mechanistic and other relevant data support the classification of glyphosate in Group 2A.
>
> In addition to limited evidence for the carcinogenicity of glyphosate in humans and sufficient evidence for the carcinogenicity of glyphosate in experimental animals, there is strong evidence that glyphosate can operate through two key characteristics of known human carcinogens, and that these can be operative in humans. Specifically:
>
> • There is strong evidence that exposure to glyphosate or glyphosate-based formulations is genotoxic based on studies in humans in vitro and studies in experimental animals.
>
> One study in several communities in individuals exposed to glyphosate-based formulations also found chromosomal damage in blood cells; in this study, markers of chromosomal damage (micronucleus formation) were significantly greater after exposure than before exposure in the same individuals.

• There is strong evidence that glyphosate, glyphosate-based formulations, and aminomethylphosphonic acid can act to induce oxidative stress based on studies in experimental animals, and in studies in humans in vitro. This mechanism has been challenged experimentally by administering antioxidants, which abrogated the effects of glyphosate on oxidative stress. Studies in aquatic species provide additional evidence for glyphosate-induced oxidative stress."

624. Because a member of Monsanto's Third Party Network of scientists, Dr. Tom Sorahan, had been designated as an invited, industry observer at the public meetings of the Working Group, the company was aware of the Working Group's likely judgements in the key areas that drive IARC determinations – animal testing, human epidemiology, and genotoxicity/possible mechanism(s) of action.

625. The IARC classification system is clearly explained and driven by the strength of published evidence in the above three areas. In one memo, it states "[w]e should assume and prepare for the outcome of a 2B rating (possible human carcinogen); a 2A rating (probable human carcinogen) is possible but less likely." (MONGLY02913526).

626. In the spring of 2015, I was among many scientists waiting for the IARC decision on glyphosate and the Working Group's report. When I learned of the Group 2A, "probably carcinogenic to humans" classification, I was surprised. I expected a Group 2B classification.

627. I read with interest that the Working Group was chaired by Dr. Aaron Blair. I had met Dr. Blair in 1982 or 1983, when he was invited to give Congressional testimony on behalf of the National Cancer Institute (Blair's employer) on cancer-causing pesticides to the subcommittee of the House Committee on Agriculture on which I served as staff director.

628. Over the years, I remained in touch with Dr. Blair, and sought his advice periodically on scientific matters. To me, the Working Group's 2A classification decision was unexpected. I knew it would trigger intense debate and might possibly lead to significant changes

in the regulation of GBH herbicides, at least in some countries and jurisdictions.

629. To better understand the thinking of the Working Group, I called Dr. Blair and had a phone conversation with him on or about March 22, 2015. He outlined the factors leading to the Working Group's decision.

630. In response to a question I asked about how strong the support was in the Working Group for the 2A classification, Dr. Blair told me that as the Working Group approached a final decision, the most extended debate was not between a 2A ("probably carcinogenic") or 2B ("possibly carcinogenic") classification, but actually between a Group 1, "The agent is carcinogenic to humans" and Group 2A ("The agent is probably carcinogenic to humans").

631. In my opinion, this information regarding the classification debate within the IARC Working Group was both unexpected and highly significant in terms of the strength of the science base supporting evaluation of glyphosate and GBH oncogenicity..

632. The fact that the Working Group almost classified glyphosate as a Group 1 carcinogen became public knowledge as a result of an Andrew Cockburn story in the September 2015 issue of *Harpers Magazine.* The story was entitled "Weed Whackers – Monsanto, glyphosate, and the war on invasive species" (https://harpers.org/archive/2015/09/weed-whackers/).

633. Cockburn's story describes the IARC classification as "a massive speed bump" undercutting Monsanto's 'mantra…all labeled uses of glyphosate are safe for human health'…"

634. To gain perspective on the IARC Working Group's assessment of the science, Cockburn interviewed Aaron Blair. The germane passage in Cockburn's story reads:

> "According to Blair, there were good grounds to declare that glyphosate definitely causes cancer [i.e., to classify it as a Group 1, *proven* human carcinogen]. This

> did not happen, he said, because 'the epidemiologic data was a little noisy.' In other words, while several studies suggested a link, another study, of farmers in Iowa and North Carolina, did not. Blair pointed out that there had been a similar inconsistency in human studies of benzene, now universally acknowledged as a carcinogen. In any case, this solitary glitch in the data caused the group to list glyphosate as a probable (instead of a definite) cause of cancer."

635. In mid-September 2014, Donna Farmer, a senior Monsanto toxicologist, learned of the forthcoming IARC review of the oncogenicity of glyphosate and glyphosate-based herbicide, and began developing a plan to respond to the forthcoming report. (MONGLY01207339).

636. A month later, William Heydens sent an email to Monsanto colleagues including Garnett, Farmer, Gustin, Koch, and Saltmiras, in which he asked: "…wouldn't an adverse IARC evaluation have the real potential to impact the results of the Annex 1 renewal [re-registration of glyphosate in the EU]." Then, he also notes:

> "And while we have vulnerability in the area of epidemiology, we also have potential vulnerabilities in the other areas that IARC will consider, namely, exposure, genotox, and mode of action."
>
> (MONGLY00989918).

[redacted]

638. A December 17, 2014 email from Kimberley Link in Monsanto's communications division to Daniel Goldstein discusses the need to identify third-party voices to tap when the IARC decision is made public. It reports that Monsanto has hired Potomac Communications to place favorable op-eds, targeting the Washington Post and USA Today, and a potential plan to approach officials in the American Academy of Pediatrics to find someone to serve as "high profile author." (MONGLY01021656).

639. A document dated 2/15/15 describes "Glyphosate Key Points Following IARC Decision," and was developed by a Heydens-Farmer-Saltmiras led team preparing for release of the IARC decision. In the event that IARC assigns glyphosate-based herbicides "an unfavorable 2B classification," the company set forth a plan that would hopefully generate an "orchestrated outcry" after the March 3-10, 2015 IARC Working Group meeting when, presumably, the final classification decision would be made and announced soon thereafter.

640. The plan set forth seven "Key Industry Points" critical of the feared, 2B classification. (MONGLY01021709-11) Seven more talking points for "Academics" are outlined, and include:

- "IARC has done a disservice by creating baseless fears with a cancer rating for glyphosate, and the confusing classification is certainly open to distortion by alarmists";
- The IARC decision "was predictable and political"; and
- "Government regulators remain reassuring about the potential risks."

641. On February 19, 2015 William Heydens sent an email to Donna Farmer, copied to Koch, Saltmiras, and Hodge-Bell, on the subject "RE: IARC Planning." The email describes "the next two most important things that we need to do…" These were a meta-analysis of epidemiology studies, and a re-assessment of Agricultural Health Study data that established a weak link between use of a glyphosate-based herbicide and multiple myeloma. (MONGLY00977267)

642. Heydens goes on to describe possible approaches to generate peer-reviewed journal articles counteracting the IARC classification. He writes that:

> "If we went full-bore, involving experts in all major areas (Epi, Tox, Genotox, MOA [Mechanism of Action], Exposure – not sure who we'd get), we could be pushing $250k or maybe even more. A less expensive/more palatable approach might be to involve experts only for areas of contention, epidemiology and possibly MOA…and we ghost-write the Exposure Tox & Genotox sections. An option would be to add Greim and Kier or Kirkland to have their names on the

> publication, but we would be keeping the cost down by us doing the writing and they would just edit & sign their names so to speak. Recall that is how we handled Williams Kroes & Munro, 2000."

(MONGLY00977267).

643. The "option" laid out in Heydens email is essentially what Monsanto did in the course of developing the papers that were published September 28, 2016 in a special, glyphosate-safety issue of the journal *Critical Reviews of Toxicology*.

644. In a detailed, internal document dated February 23, 2015, Monsanto describes its multi-faceted plan for responding to the IARC decision due to be announced in about two weeks. It provides background on IARC, and states, for example,

> "IARC has a history of questionable and politically charged rulings on the carcinogenic properties of products such as cell phones, coffee and caffeine. We should assume and prepare for the outcome of a 2B rating (*possible* human carcinogen); a 2A rating (*probable* human carcinogen) is possible but less likely."

(MONGLY02913526).

645. Attachment A to the 2/23/2015 document sets forth the "Objectives for Preparedness & Engagement" in Monsanto's response to the IARC decision. The two-bulleted items read:

- "Protect the reputation and FTO of Roundup by communicating the safety of glyphosate"; and
- "Provide cover for regulatory agencies to continue making re-registration decisions based on science."

646. Under "Strategies/Tactics" to achieve the above stated objectives, Attachment A states "Orchestrate Outcry with IARC Decision ~ March 10, 2015." (MONGLY02913530)

647. The introductory section of the full, 2/23/15 document states that: "Regulatory is not aware of a situation where a regulatory body took a different position than IARC." (MONGLY02913526).

648. The "Key Deliverables" section outlines 24 items and actions, organized by milestone date (pre-IARC decision; week of Feb. 23-27; Post-Decision/Posting, etc). These include:

- Engage Henry Miller, "Inoculate/establish public perspective on IARC reviews" (Miller produced a hard-hitting *Forbes* piece the day of the release of the IARC decision);
- Blog posts;
- Outreach to EPA/IARC participants;
- Contact journals to inquire about press releases, for "amplification of scientific studies (a Saltmiras task, which went badly awry);
- "Inform/Engage Industry Associations", with the objective "Lead voice in 'who is IARC' plus 2B outrage"; and
- Post-release of decision, "Outreach to key stakeholders," including grower groups, in order to "Neutralize impact of decision/gain support.

649. A March 17, 2015 email is sent from Eric Sachs, head of Monsanto's public affairs and outreach efforts, to Henry Miller, a long-term, glyphosate-friendly member of Monsanto's Third Party Network. In it, Sachs forwards to Miller a draft of Miller's op-ed for *Forbes* written by Monsanto and Potomac Communications.

650. Five days earlier, Sachs had emailed Miller to ask him if he would be willing to write more on the IARC decision, to which Miller replied: "I would be if I could start from a high-quality draft." (MONGLY02063615)

651. On February 25, 2015, Donna Farmer received an email from Kimberley Link informing her that "you have been selected as one of the primary spokespersons for the company to defend glyphosate." (MONGLY01210309)

652. Michael Koch, a senior official and part of Monsanto's communications team, emails Farmer seven minutes later to "discuss" this new role for Farmer in the IARC response, and writes that "In the short term I think you are the right 'fix'."

653. A flurry of emails then addresses how to rapidly gear up the Third Party Network

response, in support of Monsanto's critical reaction to the expected IARC 2B classification of glyphosate. (MONGLY01021648).

654. The communications team asks Dan Goldstein several times to identify experts that are vetted and prepared to say and write messages aligned with Monsanto's position. Such third-party experts would work with Farmer, and are needed so that the Monsanto communications team and Potomac Communications can move ahead with writing and placement of favorably, largely ghost-written op-eds.

655. Goldstein replies in a remarkable email sent 2/23/15:

> "I realize that a non-paid individual would be preferred – but I do not know anyone who has kept up with this in their 'spare time' as a toxicologist and ***one needs to be mighty prepared if one wishes to feel comfortable arguing with IARC***." (Emphasis added)

656. Goldstein estimates that a new expert would need "a good 10 hours of work in this, at $200 per hour" to accomplish the task.

657. On February 23, 2015, Kelly Clauss, another person working on Monsanto's IARC outreach and media response, emails Goldstein with a list of experts to engage in the response effort, and for work with Potomac Communications. Five epidemiologists are identified and were listed in the email in order of "most to least familiar with published studies and data." The scientists identified in her ordered list are:

- Tom Sorahan, University of Birmingham (was an invited observer at the IARC meeting);
- Pam Mink, Emory University (did one review on glyphosate-cancer studies, one on non-cancer issues, both paid for by Monsanto);
- John Acquavella, former Monsanto employee, now retired and consulting with Monsanto;
- Elizabeth Delzell, University of Alabama-Birmingham; and
- Nalini Sathiakumar, University of Alabama-Birmingham (works with Delzell).

658. Richard Garnett replies to the list and writes that "Sir Colin Berry knows

glyphosate but his contract, FCPA etc have expired so that would take 6 weeks to sort out."

659. A few days later, on February 26th, Donna Farmer responds to the now lengthy email chain on the subject "RE: URGENT: Draft email for experts to help with IARC." She begins her response to Goldstein and the communications team (Carla Lord, Kelly Clauss and Kimberley Link) with this sentence: "Help me understand why these folks were selected and who is Potomac?"

660. On February 27, 2015, about two weeks before the release of the IARC decision, Carla Lord responds to Farmer and others on the email chain, with an explanation of the plan outlined earlier in the IARC response document:

> "Donna,
>
> Thanks and I'm sorry. I didn't realize until now that you were not on the original email string (included below). Potomac is a media house that is writing op-eds and letters to editors in response to negative press surrounding glyphosate. These would be 'authored' by those on the list then placed by Potomac in media where needed. Potomac writers would do the heavy lift with the expert authors as final editor. We know these items in the media need to be from those outside the industry." (MONGLY01021648)

661. On March 14, 2015, four says after the end of the Working Group meeting and six days before the March 20th release of the embargo on the decision and publication of the results of the IARC review in *The Lancet Oncology*, Donna Farmer reported that a Monsanto colleague was on a CropLife Americas (CLA) call (pesticide industry trade association), and that an EPA representative, Jess Rowlands, announced the IARC decision to classify glyphosate as a Group 2A carcinogen. (MONGLY00977253)

662. Farmer's 3/14/2015 email was sent to Tom Sorahan, Monsanto's invited observer at the meeting, and other Monsanto colleagues including Christina Strupp, Jensen Mette, and William Heydens. These individuals were most directly involved with the IARC meeting. In the

email, Farmer restates several of the plans and talking points in the IARC response plan document. She closes it by writing: "We know it must have been a challenging week for all of you to try to keep the assessments based on sound science…"

663. Sorahan, the invited observer at the IARC Working Group meeting that, in effect, represented Monsanto, replies to Farmer and others on the email chain:

> "I do know of instances where observers at IARC felt they had been treated rudely or brusquely at Monograph meetings. That was not the case for me at Vol. 122 [the one containing the glyphosate review and classification]. I found the Chair, sub-chairs and invited experts to be very friendly and prepared to respond to all comments I made…In my opinion the meeting followed the IARC guidelines. Dr. Kurt Straif, the Director of the Monographs programme, has an intimate knowledge of the IARC rules and insists they were followed."

664. In the weeks and months after the release of the IARC decision, the nature and scope of Monsanto's "response" activities expanded.

665. Another Monsanto internal document circulated in April 2015 with the title "IARC Follow Up." Unlike all pre-decision planning documents, Monsanto is now dealing with the very serious Group 2A "probably carcinogenic to humans" classification. The goals, activities, and work products in this document include:

- "Invalidate relevance of IARC";
- "Protect regulatory FTO [Freedom to Operate]";
- "Litigation prevention/defense";
- "Protect Sales Globally"; and
- "Compilation of 3rd Party Statements in defense of glyphosate."

(MONGLY03316369-71).

666. About the same time, John Acquavella sends an email to Donna Farmer. In it, he discusses IARCs assessment and final judgements on the epidemiology data. He writes:

> "IARC's classification of the epidemiology evidence follows directly from their definition of 'limited' [evidence]. There is not really much to quarrel about with respect to the epidemiology classification."

(AcquavellaPROD00010215).

667. A draft PowerPoint entitled "Proposal for Post-IARC Meeting Scientific Projects" dated May 11, 2015, is circulated internally in preparation for a meeting. It begins by asking "Why do more?" in large letters, and then lists these reasons:

- "Severe stigma attached to Group 2A Classification";
- Aaron Blair continues to defend work & exaggerate number of studies w/association while ignoring AHS";
- "In response to our critique, can expect IARC to beef-up monograph as much as possible";
- ATSDR;
- Prop 65 [California State law requiring labeling of oncogenic products]; and
- Litigation support.

(MONGLY01228577).

668. Several new projects and scientific papers are outlined, nearly all to be authored by third-party experts. But in order to increase credibility and lower costs, "Majority of writing can be done by Monsanto" (i.e., ghost-written).

669. Most of the internal documents and emails setting forth possible post-IARC actions include discussion of the need for new, Monsanto-commissioned and controlled peer-reviewed papers providing Monsanto's critique of the basis of IARC's decision, and/or critical reviews of the findings and conclusions advanced by other scientists not adequately aligned with Monsanto's positions and messaging.

670. From the fall of 2014, about six-months before the release of the IARC decision, to mid-2015 (about 4 months after the release of the decision), these discussions led to a plan to convene a "Glyphosate Expert Panel Review" of the scientific basis for IARC's classification of glyphosate as a "probably carcinogenic to humans."

671. The "Expert Panel" idea was eventually adopted, funds were committed, and the

plan implemented, starting in late-June 2015. The panel would meet, discuss the issues, and produce a set of papers suitable for publication.

672. A detailed proposal describing several options for moving forward was presented to the "Glyphosate Strategy Team Meeting" on June 18, 2015. (Acquavella Exhibit 10-27; MONGLY03500777)

673. "**Approach A**" would entail an Expert Panel that "consists primarily of people we have worked with already…they have some/much knowledge…[and this approach would have] Lowest cost (est. $200-250k), but also lowest credibility/impact."

674. "**Approach B**" would be to add "a few 'big name' scientists & possibly some who have not worked for Monsanto before (more credibility)… hire a firm (Intertek, formerly CanTox) to manage the meeting…Cost estimate - $350-400k."

675. "**Approach C**" takes another step toward "credibility/impact" and would include hiring a well-respected risk assessment firm (presumably Intertek did not fall in this category based on Monsanto's assessment), in order to:

> "set up a totally independent review: they choose scientists, conduct meeting, write the report…Most credibility/impact but we have virtually no control…Cost estimate - $375-450k."

676. **Approach B** was the recommended path forward advanced during the meeting, and the one adopted. In fleshing out the plan, the document states: "Monsanto provides draft report which Experts edit & then publish…Use journal with quick review time…Negotiate for expedited review with journal editor."

677. A "Backup Slide" provides an even more detailed "Summary of Overall Process" and individual actions/steps include:

- "Review IARC Monograph to identify all areas that need to be addressed";

- "Prepare initial draft document";
- "Edit draft manuscript to capture meeting discussion/conclusions";
- "Send draft manuscript to Experts for their review";
- "Send manuscript to journal for review";
- "Revise manuscript per comments from journal"; and
- "Re-submit [papers] & get final approval from journal."

678. In other words, in **Approach B**, Monsanto would control the process, from producing an initial draft of the report/papers, to managing the revision of the draft in response to the meeting of the experts, making and/or approving final edits prior to submission to a journal, and managing/approving any changes made in response to peer-review comments.

679. This "Backup" slide failed to include two other key responsibilities Monsanto clearly reserved to itself – (1) deciding which names would appear on each published paper, and (2) deciding on what information would be provided to the expert panel and teams of co-authors.

680. A February 8, 2016 exchange between Monsanto consultant and *CRT* paper co-author John Acquavella and Intertek's Ashley Roberts focuses on the difficulty Intertek, Monsanto, and the third-party expert co-authors were having in reaching a consensus on who would be the listed as the author or co-authors of the summary paper in the CRT special issue.

681. Both Acquavella and Roberts wanted the entire expert panel to sign the summary. But Acquavella tells Roberts that:

> "I've had some initial correspondence from the panelists about the summary article and the consensus is that they will not be authors on an article that has inflammatory comments about IARC. Assuming those inflammatory comments were carried over from the animal carcinogenicity and genotoxicity articles, I'm sure the epi panelists would not want to be associated with those articles either. To achieve the complete authorship goal, an extensive revision of the summary article is necessary."

682. Roberts forwards Acquavella's email to Heydens, and writes: "Hi Bill, Please take a look at the latest from the epi group!!!! Can you call me once you have digested this."

683. Heydens replies the next day:

"Ashley,

OK, I have gone through the entire document and indicated what I think should stay, what can go, and in a couple of spots did a little editing."

(Heydens Exhibit 3-20).

684. The second responsibility generally reserved to Monsanto, and specifically claimed in the case of the Intertek/*CRT* paper-preparation process, was deciding what scientific materials to provide to the experts and co-authors. While Monsanto could not control access to published studies by its expert panel members, it had total control over the parts of its proprietary testing results that would be supplied to expert panel members.

685. This is evident in an August 6, 2015 email from Ashley Roberts to Donna Farmer in which she asks: "Please could you let me know in a sentence what we will be providing to the Animal Bioassay Expert group." (MONGLY01183933).

686. By the "we" in the phrase above, "what we will be providing," she really means what information will Donna Farmer/Monsanto provide to her/Intertek, so she/Intertek can then provide the information to the expert panel.

687. The 2015-2016 Intertek expert panel review of the IARC decision and monograph resulted in the publication of five papers, and a Foreword by the journal editor, Roger McClellan (all open access at http://www.tandfonline.com/toc/itxc20/46/sup1?nav=tocList). The papers included:

- Gary Williams et al., overview paper on the carcinogenic potential of glyphosate and the IARC assessment;
- Keith Solomon, assessment of exposure studies;
- Acquavella et al. on epidemiological studies;
- Gary Williams et al. on rodent bioassays; and
- Brusick et al. on weight of evidence evaluation of glyphosate, formulated glyphosate herbicides, and AMPA (major glyphosate metabolite).

688. Roger McClellan was aware of the scrutiny his journal's special issue on

glyphosate safety would receive. On multiple occasions, he stressed in exchanges with Ashley Roberts, the employee of Intertek that managed the process of developing the papers, the importance of clarity and full transparency in the Acknowledgements and Declaration of Interest sections of the papers.

689. In a June 19, 2016 email to Roberts, McClellan writes:

> "I am still concerned about the tone in some places. Why antagonize the reader? I am still not clear as to the process used by all of the Panels. These reports are essentially a rebuttal of the IARC process and conclusions. There appears to be a reluctance to be absolutely clear in presenting exactly what IARC concluded, the panels conclusions and how they differ. Am I missing something?"

(MONGLY02360733-34).

690. Six days later, Roberts replies from vacation. She states that "I am getting a lot of pressure to publish the papers for a lot of reasons as you can imagine." She then asks for the specific changes McClellan wants in the Acknowledgements and Declaration of Interest (DOI) statements.

691. Just 90 minutes later, McClellan responds to Roberts. He spells out the changes he wants in the Acknowledgements (thank the reviewers for extensive comments received). He also says that "The Acknowledgements section should also identify any other reviewers of the paper and any editorial assistance." (MONGLY02360732).

692. In reference to the DOI, McClellan writes that it should:

> "…make clear how individuals were engaged, i.e. by Intertek. If you can say without consultation with Monsanto that would be great. If there was any review of the reports by Monsanto or their legal representatives that needs to be disclosed."

693. Each of the papers has a similar "Declaration of Interest" statement. The "Declaration of Interest" statement in the Brusick et al paper is quoted below:

> "The employment affiliation of the authors is as shown on the cover page.

> However, it should be recognized that each individual participated in the review process and preparation of this paper as an independent professional and not as a representative of their employer….[Past and current relationship of each co-author to Monsanto is then listed]"
>
> "The Expert Panel Members recruitment and evaluation of the data were organized and conducted by Intertek Scientific & Regulatory Consultancy…"
>
> "Funding for this evaluation was provided by Monsanto Company which is a primary producer of glyphosate and products containing this active ingredient. Neither any Monsanto Company employees nor any attorney reviewed any of the Expert Panel's manuscripts prior to submission to the journal."

694. Based on my review of the detailed correspondence between Intertek and Monsanto and co-author, I conclude that the first paragraph in the above quoted DOI is presumably truthful, the second paragraph is not truthful, and the second sentence in the third paragraph is not truthful.

695. Via direct interactions with Roberts of Intertek, it is clear that Monsanto reviewed and approved of the content of the papers prior to submission, and again after the papers were revised in response to peer review comments.

696. The expert panel evaluation, and the composition of the panel itself, was controlled by Monsanto. Indeed, a July 1, 2015 email from William Heydens to Ashley Roberts, the woman running the Monsanto project for Intertek, Heydens tells Roberts "we" (Monsanto) are adding two additional scientists, and that: "We just learned this morning that we can't have you send out 'invitations' until the names have been approved by our legal group." (MONGLY00992949-51).

697. Monsanto was heavily involved in all stages of paper preparation, from deciding on the information that would be provided to the co-author teams by Intertek; producing drafts of the papers, or sections of papers provided to the teams; deciding on whose name(s) would appear

on the papers; interacting with the teams on how to address key issues; responding to review comments; and, the final stages of editing.

698. Heydens, in particular, played a direct, hands-on role.

699. An August 28, 2015 email to Donna Famer and other Monsanto colleagues from Heydens circulates for comment his first draft of the Intertek Expert Panel report on the carcinogenic potential of glyphosate. (Acquavella Exhibit 10-30; MONGLY02844211).

700. In the draft Heydens circulated, "William Heydens" does not appear as a co-author, nor does his name appear on any of the papers as published. In failing to truthfully acknowledge authorship and declaring in the conflict of interest disclosures that Monsanto employees played no role in the review of the papers, Monsanto violated ethical norms governing scientific publishing, including the policies of the journal *Critical Reviews in Toxicology*.

701. Heydens was influential, if not responsible for many critical decisions about how strongly to make positive statements regarding the safety of glyphosate and Roundup herbicides, and how sharply to criticize the IARC report and the studies in the peer-reviewed scientific literature that the IARC working group relied upon in reaching its "probably carcinogenic to humans" classification.

702. For example, Heydens sharply disagreed with some panel-members, and ex-employee Acquavella over how strongly to state criticisms of the IARC classification decision. Examples of such disagreements are evident throughout Heydens' track-changes comments and editing of Acquavella's edits to the draft of the summary panel report. (MONGLY01000680-01000709).

703. Aquavella's paper on the epidemiological data is an outlier in two ways. The list

of co-authors appears to accurately represent the contributions of different people to the paper. The Acquavella et al. paper also contains a different version of the statement regarding Monsanto's role in the review of the papers; the Acquavella et al. DOI states "The authors had sole responsibility for the content of the paper, and the interpretations and opinions expressed in the paper are those of the authors."

704. On September 28, 2018, the Editor of *Critical Reviews in Toxicology* (*CRT*) and the publisher of the journal (Taylor and Francis) issued an "Expression of Concern" via its website that was also subsequently published in the journal (https://doi.org/10.1080/10408444.208.1522786).

705. The "Expression of Concern" states in large part:

> "We…have been informed of concerns over the completeness of acknowledged contributions [to the special glyphosate issue]…and in declarations of interest provided by the named contributors, for the following articles: [the five core papers in the issue are then listed]."
>
> "We have requested corrigenda from the authors to provide additional disclosure as to the contributions to the articles. To date, we have only received corrigenda for three of the five articles that have been agreed to by all the authors. We have not received an received an adequate explanation as to why the necessary level of transparency was not met on first submission. We thank those who brought this to our attention."

706. In my opinion, the Declaration of Interest statements accompanying the papers in the *CRT* special issue on glyphosate were not just incomplete, they were blatantly untruthful, as evident in the email traffic discussed above.

707. It is also my opinion that if the Editor of *CRT* and Taylor and Francis ever come to understand the full degree to which Monsanto controlled the production of these five papers, as documented in this report, they will retract all the papers and issue an apology to its readers.

### D. Political and Other Activities Post-IARC

708. In my opinion, the breadth of Monsanto's activities in response to the IARC

classification of glyphosate herbicide as a probable human carcinogen is striking. A June 5, 2015 update on "US Government Outreach – WHO IARC Classification on Glyphosate" outlines dozens of ongoing and proposed actions and goals. Under "**THE STRATEGY**", the document states:

> "One strategy for addressing widespread confusion in the wake of the IARC classification has been to seek clarification from the World Health Organization (WHO) which would provide the proper context of the classification for governments and regulators around the world to have greater confidence defending their science based regulatory decisions."
>
> (MONGLY02953363).

709. The document reports on multiple briefings given to U.S. government agencies, including a Donna Farmer briefing of Dr. Mitchell Wolfe, the Deputy Assistant Secretary for Global Heath, in the of Department of Health and Human Services (HHS), to which "we came prepared with a robust set of technical materials for the Secretary's background…".

710. In the briefing for HHS Deputy Secretary Dr. Wolfe, he was told about ATSDR (Agency for Toxic Substances and Disease Registry), an agency under HHS of which he was reportedly unaware. Monsanto then told Wolfe about the ongoing ATSDR review of glyphosate, and made the case that such a review was unnecessary, and that the EPA bears the primary responsibility for "determination of pesticide safety."

711. Then Monsanto briefed Wolfe on "A common element between IARC and ATSDR…Christopher Portier Ph.D…[who] was Director of ATSDR and co-chair of the IARC Advisory Group."

712. Dr. Portier's views on glyphosate oncogenicity were discussed, as was the fact that Dr. Portier "was an invited specialist representing the Environmental Defense Fund."

713. According to Monsanto's recounting of the meeting "Dr. Wolfe said he would

follow up on what was going on with ATSDR and he was encouraged to have discussions with the EPA staff, as well."

714. Last, Monsanto asked for Wolfe's and HHS's "assistance in securing a WHO clarification. We emphasized that we were not seeking changes to IARC, the classification or the IARC process."

715. In fact, Monsanto had already initiated, and is still carrying out campaigns to punish IARC for its classification through, among other things (details below):

- Lobbying members of Congress to challenge U.S. government funding for IARC, via U.S. government support for the WHO;
- Calling for Congress to hold hearings;
- Mounting a campaign to force IARC to release drafts of its glyphosate review document and notes from Working Group deliberations;
- Working with a Washington Post reporter purportedly doing a hit piece; and
- Mounting multi-faceted outreach and third-party expert criticisms of the IARC process, the people who participated in it, the conclusion it reached, and its accountability.

716. Accordingly, in my opinion, the statement in Monsanto's account of the Wolfe-HHS briefing that "…we were not seeking changes to IARC, the classification or the IARC process" was not truthful.

**E. Blocking the ATSDR Review of Glyphosate**

717. Another important Monsanto action-item, post-IARC, was stopping an ongoing ATSRD review of glyphosate safety.

718. An ATSDR review that supported IARC's conclusions and classifications was to be avoided. (MONGLY03342947).

719. In response to the ATSDR review, Monsanto:

- Sought and carried out meetings, briefings, and webinars with ATSDR to communicate its assessment of the issues, explain why it felt the ATSDR review was unneeded, and the scientific flaws in the IARC review;

- Received significant help from two senior OPP/EPA officials – Jess Rowland and the OPP Director, Jack Housenger;
- Sought assistance and support from the Deputy Assistant Secretary for Global Health in HHS (the agency home of ATSDR);
- Asked Monsanto's home-state Senators to contact HHS and reinforce the urgency of quick HHS action to intercede with ATSDR, given information Monsanto had obtained suggesting the ATSDR report might be released in only a few weeks;
- Lobbied Congresswoman Lynn Jenkins to submit questions regarding the ATSDR glyphosate review to the Secretary of HHS at the conclusion of a hearing before the House Ways and Means Committee on health care reform (MONGLY03064699); and
- Recruited individuals to write letters to Congressmen complaining that the ATSDR review was duplicative and a waste of taxpayer money, so that the letter(s) could be used to trigger media coverage of the campaign to stop the ATSDR study. (MONGLY03342947)

720. In my opinion, a reasonable and prudent pesticide manufacturer would not attempt to prevent a regulatory agency from conducting a safety review, especially when there is concern that review may result in a safety finding.

## XIII. Downplaying Glyphosate Risks

721. Pesticide companies bear an obligation vested in various laws and regulations, and common corporate decency, to assure that the products they bring to market are safe and will reliably produce the benefits for which they are registered, i.e., control of weeds in the case of glyphosate-based herbicides.

722. The term "product stewardship" is used within the industry and regulatory agencies to describe and encompass the actions pesticide manufacturers should take on an ongoing basis in the interest of product stewardship, before and after a new use of a pesticide is approved.

723. In the pesticide arena, the sciences supporting both human-health risk assessments and environmental-impact assessments are dynamic and imperfect, and heavily dependent on location- and even application-specific data, which are almost never available on a large scale. So, in companies and regulatory agencies alike, many assumptions and a considerable degree of judgement is essential in deciding upon the science that must be conducted prior to seeking and approving a new use of a pesticide.

724. Where to draw the line between presumably safe and possibly risky pesticide uses is also fraught with scientific, social, and political challenges, uncertainty and tension.

725. The same is true after approval, as companies and regulators strive to refine and agree on the nature and magnitude of risks after a pesticide is approved and has been applied for a period of time.

726. But in general, Monsanto claims that they base all their product development, testing, commercialization, and regulatory actions on the best available science. Such science is often produced and communicated by pesticide registrants in the hope of altering the outcome of

risk assessments conducted by regulators, especially when existing estimates of risk point to potential problems (e.g., a risk that exceeds the EPA's "level of concern").

727. The crux of most protracted and contested regulatory confrontations over the last half-century has been debate over what the "best" or "soundest" science shows relative to the balance of pesticide risks and benefits.

728. This is the case with glyphosate and Roundup herbicides.

**A. Freedom to Operate (FTO)**

729. Tensions often arise between the commercial interests of a pesticide manufacturer and what the latest and best science suggests is the most responsible way to manufacture and sell a given pesticide.

730. In Monsanto, protecting the Freedom to Operate ("FTO") in the manufacture and sale of glyphosate-brand herbicide was a clearly expressed objective across the company.

731. Monsanto's John Acquavella makes the case for one such investment in science as part of a proposal for a new, industry-funded, multi-pesticide non-Hodgkin lymphoma study.

732. The goal of the study, among other things, would be to respond to the positive glyphosate-NHL results in the Hardell-Eriksson, and the forthcoming epidemiological study results from the National Cancer Institute's "Agricultural Health Study":

> "There are a number of reasons why industry should consider this proposal seriously. First, allegations that pesticides cause cancer are important to the business and regulatory climate for pesticide manufacturers and, indeed, companies have ***a product stewardship obligation*** to ensure that their products can be used safely."
>
> (Emphasis added, MONGLY00894005).

733. Monsanto did not follow Acquavella's advice and has never conducted an epidemiological study to evaluate the relationship between NHL and Roundup formulations.

### 1. Section 6(a)(2) of FIFRA

734. Section 6(a) (2) of FIFRA, discussed earlier, is a provision in federal law intended to vest responsibility on pesticide registrants to report to the EPA any information, data, or new insights regarding pesticide risks that are gained by the registrant, regardless of the source of the information.

735. The June 1986 Registration Standard for glyphosate contains this passage: "Registrants [at this time for glyphosate, only Monsanto] are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information…***including interim or preliminary results of studies***, if those results suggest a possible adverse effect on man or the environment. This requirement continues as long as your products are registered by the Agency." (page 3) (Emphasis added).

736. In my opinion, there are multiple instances in the record of where Monsanto did not disclose information that might suggest a new or heightened risk from use of glyphosate-based herbicide. Some information not properly disclosed under Section 6(a)(2) arose from the company's inhouse research or commissioned studies (e.g,. the TNO rat skin penetration study or the Parry reports), while other information was learned from the experience of users of the company's products.

### 2. Responding to FQPA Challenges

737. Passage of the Food Quality Protection Act ("FQPA") in 1996 changed the basic standard and rules governing the setting of food-additive tolerances for pesticide known to be oncogenic, including glyphosate beginning in 1983. Implementation of the FQPA required EPA to deal with dozens of science and risk assessment policy issues over several years, some of which had potential impacts on a number of Monsanto products, including glyphosate.

738. Monsanto established an "FQPA Core Team to engage with EPA as it developed FQPA policies and procedures, and to alert colleagues of possible implications for the labels and tolerances sanctioning use of specific Monsanto pesticide products." (MONGLY03750989)

739. Abby Li [FND/1735] was a member of this FQPA Core Team. She sent a November 20, 1999 email to several Monsanto management team and senior officials regarding the activities of the FQPA Core Team. After listing the six members of the FQPA Core Team, the email stated:

> "This [membership] is a good mix of people that allows us to have external influence as well as ensure that we have practical understanding of the full impact to our products. I'd like to make sure we push hardest on those issues that are threatening our business."
>
> (MONGLY03750989).

740. Two days earlier, on November 18, 1999, Abby Li sent an email to 10 Monsanto colleagues regarding a scoping session on the evolving OPP policies governing aggregate risk assessment under the FQPA. (The FQPA directed the EPA to take account of exposures to a given pesticide from water, food, occupational, atmospheric, and any other routes of exposure; such total estimates of exposure from all routes are called "aggregate exposure" in the context of FQPA implementation).

741. The email begins: "Dear people who might be interested in the FQPA…" The last paragraph addresses the membership of the FQPA Core Team and key areas of expertise that need to be represented. Then, Abby Li writes: "A key goal is to understand how our products are impacted so we know what issues Monsanto should fight the hardest on." (MONGLY03750990).

742. This stated goal of FTO runs directly counter to Monsanto's stewardship responsibilities as a registrant for GBHs and, in my opinion, a reasonable and prudent pesticide manufacturer would not align its stewardship around FTO objectives.

### B. Understating Risks

743. In the discovery records in this case that I have reviewed, there are dozens of examples where Monsanto employees, consultants, Third Party Network scientists, and PR firms prepare and share written materials that overstate the certainty of some things (e.g., "get up and shout glyphosate is non-toxic"), and downplay the significance of other known facts (e.g., glyphosate-based herbicides are genotoxic in some tests).

744. In an episode described in detail earlier, Monsanto officials substantially mischaracterized statements made by third-party experts that Monsanto had brought to an EPA Scientific Advisory Panel meeting.

745. The inaccurate statements were contained in a letter from Monsanto's senior U.S. registration specialist to EPA after the SAP meeting. The letter asserted that Monsanto's invited guests testified at the SAP meeting that a repeat of the controversial Bio/dynamics mouse study was not warranted, when none of the invited experts made such a statement.

746. Other examples of overstating benefits or understating risks are discussed below.

#### 1. The IARC Review Process

747. In 2014, Monsanto initiated a number of activities to potentially influence the decision reached by the IARC Working Group assessing glyphosate carcinogenicity.

748. IARC procedures and policies are clearly stated and well known. For example, see the 2015 published paper "IARC Monographs: 40 Years of Evaluating Carcinogenic Hazards to Humans" (Donna Farmer Exhibit I-44; or access online https://ehp.niehs.nih.gov/wp-content/uploads/123/6/ehp.1409149.alt.pdf).

749. IARC Working Groups review and rely only on the results, insights, and information in scientific papers published in peer-reviewed journals. Unpublished studies

conducted by companies, or papers in the publication process, but not accepted, are not considered.

750. Thus, Monsanto worked to get two papers published before the end of the IARC review process, so that both would be among those in the peer-reviewed literature, and hence eligible for consideration by the IARC Working Group.

751. Both papers had been in preparation for some time and included a paper by Kier on genotoxicity and one by Greim et al. on the results of rodent bioassays.

752. Regarding the Kier publication, Monsanto commissioned and paid for a review article focused on genotoxicity biomonitoring studies.

753. Larry Kier, then a consultant to Monsanto and a former, long-term employee, wrote the paper, which was submitted to Roger McClellan, Editor of the journal *CRT*. This journal had been used several times by Monsanto to recycle in a peer-reviewed journal the company's proprietary, internal studies, findings, criticisms of the work of other scientists, and assessments of glyphosate risk-assessment issues.

754. The 2015 *CRT* paper by Kier was entitled "Review of genotoxicity biomonitoring studies of glyphosate-based formulations" (Vol 45(3): pages 209-218; accessed 12/10/17 at http://www.tandfonline.com/doi/pdf/10.3109/10408444.2015.1010194?needAccess=true).

755. The paper's "History" declaration states that the initial paper was submitted to *CRT* on January 7, 2015 and was revised by the author and submitted back to *CRT* on January 17, 2015. It was accepted for publication by the journal the next day, January 18th, and published online February 16, 2015, or about one month before the March 3-10, 2015 final meeting of the IARC Working Group conducting the glyphosate assessment.

756. Accordingly, 11 days transpired from the date of the original submission to the

acceptance of the Kier paper. This meant that the peer review process, the editor's assessment of the reviewer comments, the author's revisions in response to peer-review comments, submission back to the journal, the editor's consideration of the author's response to reviewer comments, and decision to accept and publish all occurred in 11 days—a staggering pace.

757. I have published about three-dozen peer-reviewed papers. Between several months to about one year transpired between initial submission and acceptance of each of them, a time-frame that is typical of most papers, and most peer-reviewed science journals.

758. Over the last 30+ years, I have served many times as a peer-reviewer of papers submitted for possible publication. It generally takes a few weeks to two months for me to complete and submit such reviews. Another 1-2 months typically transpires before I hear back from the journal, with an invitation to read and react to the changes in the paper done in response to my, and other review comments. Then, another 1-2 months is required prior to final acceptance and the paper being published online or in a journal.

759. In my opinion, in the history of scientific publishing in widely read journals, very few, if any, papers have matched the speedy process of the Kier (2015) *CRT* paper through peer-review to publication. There had to have been an extraordinary set of circumstances driving the pace of the publication process for this paper.

760. On February 19th, a few days after the Kier (2015) *CRT* paper was published online, an email exchange occurred between the paper author, Larry Kier, the journal editor Roger McClellan, and Monsanto's David Saltmiras.

761. The email chain starts on 2/19/17 with an email from David Saltmiras to *CRT* editor McClellan that begins "Roger – FYI on press releases." This email was not cc'd to the lead authors of the papers: Kier and Greim.

762. The email focused on the content of promotion material that Saltmiras had drafted and sent to the journal editor, for use by the journal and its publisher in promoting the papers. The material drafted by Saltmiras covered both the Kier (2015) and Greim et al (2015) papers. Saltmiras included a request that McClellan and the publisher take steps to raise the visibility of the papers. (MONGLY01087311-17)

763. The Saltmiras email to McClellan advances "Sound bytes for social media."

764. A few hours later in response to the suggestion from Saltmiras, McClellan sent an email to Charles Whalley, a senior manager at the publishing company Taylor and Francis (T and F) that puts out *CRT*. The email begins:

> "I spoke with David Saltmiras today concerning the two Glyphosate papers that will be the lead papers in the next issue of Critical Reviews in Toxicology with regard to F and F [referring to T and F, the first "F" in the original text is a typo] putting out any publicity on these two papers. The email below includes complete citations for the papers, abstracts and some information developed by Monsanto Company on the papers."

765. The McClellan email to Whalley goes on to state the relevance of the Kier (2015) paper to the ongoing IARC glyphosate review, and then writes:

> "As a bottom line the two papers [Greim et al. and Kier] published on line in *CRT* are likely to attract some attention in the scientific and regulatory community and, possibly, by lay media."

766. McClellan then asks about Taylor and Francis policies regarding the publisher's promotion of just-released papers and asserts that the two papers "would be excellent candidates" for such a promotional effort by the publisher.

767. As a courtesy, McClellan also sent a copy of his 2/19/17 email to David Saltmiras and Larry Kier. Just under a half-hour later, Kier responded by email to *CRT* Editor McClellan. He begins: "I'm a little cautious about high levels of publicity for the biomonitoring review and have concerns about some of the suggested publicity material." (MONGLY01087312).

768. Kier then writes: "I don't know who wrote the 'Summary' for my paper and certainly don't want to offend them but it is not the way I would have worded it and I would personally not want this used to characterize my paper."

769. The differences between the "Summary" of Kier's paper sent to McClellan by Saltmiras, and presumably written by him, and the revised "Summary" Kier wrote and included in his email to McClellan are significant.

770. The key passages from the Saltmiras-submitted "Summary" of Kier's paper read: "The author concluded that there are no direct risks to human DNA under normal exposure conditions" and "these results confirm previous conclusions that glyphosate-based herbicides do not damage DNA in humans following real world exposures."

771. The comparable passages that Kier wrote for a revised "Summary" of his paper read: (1) "The author concluded that these studies [on genotoxicity] do not indicate significant genotoxic risks to humans from glyphosate-based herbicides under normal exposure conditions"; and (2) "These findings are consistent with an earlier review of an extensive number of laboratory studies that indicated little likelihood of significant genotoxic risk or reaction with DNA under normal exposure conditions."

772. The Saltmiras version of sentence is unequivocal – "there are no direct risks to human DNA." Kier's rewrite of (1) includes an important change. Instead of "no risk," Kier writes that there is an absence of "significant genotoxic risks."

773. In key passage (2) quoted above, the Saltmiras version states that glyphosate-based herbicides "do not damage DNA in humans." Kier's rewrite says that there is "little likelihood of significant genotoxic risk or reaction with DNA under normal exposure conditions."

774. This version contains three caveats. First, there is "little likelihood," but hence some chance of "significant genotoxic risk or reaction" under normal conditions. Second, Kier leaves the door open for less than "significant" genotoxic risk or reaction under normal conditions. Third, under not "normal," and presumably high-exposure scenarios, there would be heightened likelihood of modest to significant genotoxic risk.

775. In the same email to McClellan, Kier then turns his attention to the "Sound bytes for social media" in the Saltmiras email from earlier the same day. The sound bites state that glyphosate-based herbicides "do not damage cellular DNA…" and are "not associated with DNA damage in human cells." About these statements, Kier writes:

> "I also don't think the 'Sound bytes for social media' are accurately worded. They are way too absolute for my taste and place undue emphasis on the strength of the biomonitoring data. Unfortunately, I can't readily suggest alternatives that fit nicely into the 'sound byte' format."

776. Nine minutes later at 5:12 p.m., after receiving the above described email from Kier, *CRT* Editor McClellan responds to Kier, sending a copy to Saltmiras. He writes:

> "Larry:
>
> What I forwarded to T and F (Charles Whalley) is what I received from David Saltmiras. I assumed you were in the loop on what had been developed at Monsanto. I suggest you get in touch ASAP with David."

777. Around noon the next day, Larry Kier does email David Saltmiras. His message is terse and to the point, and quoted in full below:

> "David,
>
> I think I might have misunderstood something in our earlier conversation today but apparently the Summary and Sound bytes were from Monsanto.
>
> Please consider the bcc: comments I sent earlier to Roger. While I definitely support glyphosate and GBF's [glyphosate-based formulations] I really don't want to have ***inappropriate absolutes*** representing this [Kier, 2015] review."

(Emphasis added; MONGLY01087311).

**2. Advertising**

778. In June 1988, a member of the medical school faculty at the University of Iowa saw an advertisement for Roundup herbicide on TV, depicting an application of the herbicide. The person in the advertisement was wearing gym shoes, a short sleeve shirt, and long pants. He called the EPA to raise concern over the safety of such a method of application under the conditions depicted in the advertisement.

779. Edwin Tinsworth, then Director of the OPP Registration Division, wrote a July 26, 1988 letter to Dr. Timothy Long, then Roundup's Registration Manager, stating that: "We are concerned that advertisements for Roundup (running through July in Iowa and perhaps other soybean growing areas) show the product being applied in a manner inconsistent with protective clothing requirements…and we request that you cease running these spots."

780. In a certified letter dated April 7, 1992 to Monsanto, Leo Alderman of the Toxics and Pesticides Branch in EPA Region VII challenges misleading claims made in Monsanto advertising literature promoting Roundup sales. These statements included "Roundup doesn't stay in the soil, won't leach to nearby plants and breaks down into natural substances…Nothing kills weeds better, or easier, than Roundup…Biodegradable."

781. He instructs Monsanto that "such statements should be removed from all literature advertising the product…" Alderman directs Monsanto to cease distributing all advertising material with such claims and that Monsanto send him/EPA copies of the revised advertising material within 30 days.

782. In 1996, the Consumer Frauds and Protection Bureau of Attorney General of the State of New York brought an action against Monsanto over assertions and safety claims in

multiple print adds appearing in publications distributed in the State. (MONGLY02510516-544)

783. The Attorney General found that Monsanto advertising claims that Roundup herbicides:

- "…are safe and will not cause harmful effects to people…";
- Are safe "because they quickly break down into natural substances"; and
- Are "good for the environment".

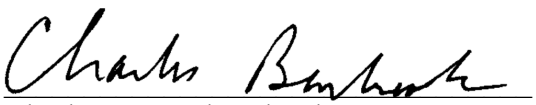
784. In addition, the AG states that Monsanto advertising asserts or implies that "The characteristics of Monsanto's glyphosate-containing pesticide products can be adequately described by the characteristics of glyphosate alone." (MONGLY 02510519).

785. The AG found "that the representations set forth in paragraphs E and F above [encompassing the above quoted claims] constitute false and misleading advertising." After presenting why Monsanto's advertising claims were false and misleading, the AG reports agreement from Monsanto to cease and desist making all such claims in advertising associated with the marketing of Roundup in New York.

786. In my opinion, the New York AG was correct to challenge the basis of multiple claims in Roundup advertising.

787. In my opinion, Monsanto underperformed in its responsibility to dissuade false and dangerous assertions and statements regarding the risks associated with exposures to Roundup. One of the common, and most dangerous assertions often encountered is that "Roundup is safe enough to drink." This is simply not true.

These are my opinions, and basis therein, to a reasonable degree of scientific certainty.



Charles M. Benbrook, PhD.
Nov. 10, 2018

# Appendix A Resume

July 20, 2018

# CHARLES M. BENBROOK


**BUSINESS AND HOME ADDRESS** [redacted]

**PHONE** [redacted] (Business)
[redacted] (Cell, works only when traveling)
**E-MAIL** -- [redacted]


## PERSONAL INFORMATION

Birthdate: [redacted]
Place: [redacted]
Children: [redacted]
Wife: Karen Lutz Benbrook
Hobbies: Fishing, Raising Rabbits

## EDUCATION

B.A. Degree - Economics, Harvard University (1971)
M.A. Degree - Agricultural Economics, University of Wisconsin (1979)
Ph.D. - Agricultural Economics, University of Wisconsin (1980)

## EMPLOYMENT HISTORY

Visiting Scholar, Bloomberg School of Public Health, Johns Hopkins University, March 31, 2017-present

Visiting Professor, Newcastle University, Newcastle, U.K. 2016-Present

Benbrook Consultant Services (BCS), President. December 1, 1990 to present.

> Analytical services for domestic and international clients in the public and private sectors. Areas of focus include biotechnology; pesticide use, risks, and regulation; adoption and costs-benefits of Integrated Pest Management; impacts of federal environmental and food laws, especially the Food Quality Protection Act of 1996. BCS specializes in the development of novel methodologies to assess environmental and public health risks and issues.

Washington State University, Center for Sustaining Agriculture and Natural Resources, Research Professor. August 16, 2012 to May 15, 2015.

Adjunct Faculty, Department of Crop and Soil Sciences, Washington State University, October 31, 2007 to August 26, 2015

Research scientist and program leader for the "Measure to Manage Program – Farm and Food Diagnostics for Sustainability and Health."

The Organic Center, Chief Scientist. January 1, 2006 to May 31, 2012.

Developed and managed a program of research on the environmental and consumer health benefits of organic foods and farming.

National Research Council/National Academy of Sciences, Washington, D.C. Executive Director, Board on Agriculture. January 16, 1984 to November 30, 1990.

Responsible for overseeing and managing activities of the Board. Major BA/NAS reports published during this period addressed the methods and applications of agricultural biotechnology; unique risks faced by infants and children from pesticide exposure; resistance to pesticides; options to improve the nutritional composition of animal products; and, agricultural research and education.

Subcommittee on Department Operations, Research, and Foreign Agriculture, Committee on Agriculture, U.S. House of Representatives. Subcommittee chaired by Congressman George E. Brown, Jr., Staff Director. April 1981 - January 13, 1984.

Responsibilities included: (i) preparing and analyzing legislation within the jurisdiction of the subcommittee; (ii) organizing subcommittee hearings and business meetings; and, (iii) briefing members and staff on legislation and oversight activities.

Council on Environmental Quality, Executive Office of the President, Agricultural Policy Analyst. December 1979 - March 1981.

Represented CEQ on various Executive Branch committees; analyzed natural resource data and policy options; and (iii) conducted research and contributed to multiple Executive Branch reports.

**AWARDS and HONORS**

Excellence in Science Award, OTA/TOC Dinner, March 2014.

Appointed as member, USDA's AC 21 agricultural biotechnology advisory committee, 2010, and reappointed in 2013.

Appointed to AGree Advisory Committee, 2010.

Appointed as Adjunct Faculty Member, Department of Crop and Soil Sciences, Washington State University, Pullman, Washington, 2007.

Graduated cum laude from Harvard University, 1971.

Received $1,000 cash award from the Council on Environmental Quality for contributions to the completion of the National Agricultural Lands Study.

## LITIGATION HISTORY

In addition to the above activities, Benbrook has participated in several lawsuits involving pesticide use and risks, agricultural biotechnology, and food labeling. The major cases are listed below:

1. Peterson, et al. v. BASF Corp. Plaintiff's attorney, Hugh Plunkett, Lockridge Grindal Nauen, St. Paul, Minnesota. Trial Ada, Minnesota, in the District Court for Northeastern Minnesota (Red River Valley)

2. James E. Fox, et al. v. Cheminova, Inc USDC, EDNY Case Number CV 00-5145, plaintiff's attorney Kevin Huddel, Jones, Verras, and Freiberg, LLC, New Orleans, Louisiana.

3. Ricardo Ruiz Guzman individually, Martin Martinez individually, and Miguel Farias and Ignacia Farias, husband and wife v. Amvac Chemical Corporation. Plaintiff's attorney, Richard Eymann, Eymann, Allison, Hunter, Jones, P.S., Spokane, Washington.

4. United Industries v. Dow AgroSciences. Plaintiff's attorney, Dudley Von Holt, Thompson Coburn LLP, St. Louis, Missouri.

5. Hardin, et al. v. BASF, U.S. District Court for the Eastern District of Arkansas. Plaintiff's attorney, William French, Looper Reed and McGraw, Dallas, Texas.

6. Timm Adams, et al. vs. U.S.A., et al., Idaho U.S.D.C. Case No. CIV 03-049-E-BLW, Plaintiff's attorneys, Holland and Hart, Boise, ID and Denver, CO.

7. Jim Aana, et al., vs. DuPont Pioneer and Gay Robinson, Inc. Civil No. CV12 00231 – LEK-BMK, United States District Court, District of Hawaii.

8. Conagra Foods, Inc, Case re Wesson oils, No. 11-cv-05379-MMM, U.S. District Court Central District of California Western District.

9. Laura Eggnatz, Katrina Garcia, and Julie Martin v. Kashi Company. Civil Case No.: 12-21678-CIV-Lenardo/O'Sullivan, U.S. District Court, Southern District of Florida, Miami Division.

10. Grocery Manufacturers Association et al. Plaintiffs, v. William H. Sorrell, Attorney General of Vermont, et al., Case No. 5:14-cv-117, United States District Court for the State of Vermont.

11. Barron v. Snyder's-Lance, Inc. No. 0:13-cv-62496-Leonard-Goodman (S.D. Fla.).

12. In re General Mills, Inc. Kix Cereal Litigation, Case No. 12-249 (KM) (JBC),U.S. District Court of New Jersey

13. Dewayne Johnson v. Monsanto Company, Case No. CGC-16-550128, Superior Court State of California County of San Francisco.

**RESEARCH and ANALYTICAL ACTIVITIES**

1979-1983: Basic analytical work on the extent and distribution of soil erosion, findings used in development of the conservation provisions in the 1985 farm bill.

1981- 1983: Congressional oversight investigation of the pesticide regulatory activities of the Environmental Protection Agency, wrote a three-volume subcommittee report: "EPA Pesticide Regulatory Study." The report's findings and recommendations set in motion activities that led to the 1984-1987 NAS report *Regulating Pesticides in Food: The Delaney Paradox* (1987), the seminal 1993 NAS report *Pesticides in the Diets of Infants and Children,* and passage of the "Food Quality Protection Act" in 1996.

1988-1989: Compiled data and conducted analysis of private sector research investments in the food and agricultural industries, leading to Appendix B, "Private Sector Research Activities and Prospects", in *Investing in Research: A Proposal to Strengthen the Agricultural, Food, and Environmental System*, NAS Press, 1989.

1995-2000: Developed the first system in the U.S. that quantifies the level of adoption of Integrated Pest Management along the "IPM continuum." This early model of IPM adoption has been refined and augmented through several iterations and applications in multiple projects, some of which are ongoing.

1999-2004: Developed a method to estimate the usage of subtherapeutic antimicrobials in livestock production for growth promotion and disease prevention. Did the analytical work and was principle author of the Union of Concerned Scientists' report *Hoggin It! Estimates of Antimicrbial Abuse in Livestock* (2001).

2004-June 2012: Developed the "Nutritional Quality Index" (NQI), a food nutritional profiling system encompassing 26 essential nutrients. For the first time ever, applied the system to all foods consumed in a day by an individual. Utilized model in assessment of the fatty acid profile of organic versus covnentional whole milk.

2013-2014: Posted on the M2M website at Washington State University interactive systems allowing access to: (i) USDA pesticide use data by crop, state, and over time in the U.S., and (ii) detailed information on pesticide residues and risk levels in food, for organic and conventional food, and imported foods and domestic production.

## REPORTS, ARTICLES, AND PRESENTATIONS

Benbrook has published over 30 articles in peer reviewed journals, spanning multiple disciplines including agricultural biotechnology, pesticide use and residues in food, soil and water conservation, pesticide risk assessment methods, Integrated Pest Management, nutrition, germplasm conservation, scientific basis for evaluating agricultural technologies, antibiotic use and resistance, food safety, international agricultural development, sustainable agriculture, and agricultural policy.

### Peer Reviewed Papers and Articles

Benbrook, C. 2018. Why Regulators Lost Track and Control of Pesticide Risks: Lessons from the Case of Glyphosate-Based Herbicides and Genetically Engineered-Crop Technology. Cur Envir Health Reports. https://doi.org/10.1007/s40572-018-0207-y

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Vandenberg LN, Blumberg B, Antoniou MN, Benbrook CM, Carroll L, Colborn T, Everett LG, Hansen M, Landrigan PJ, Lanphear BP, Mesnage R, vom Saal FS, Welshons WV, Myers JP. 2017. Is it time to reassess current safety standards for glyphosate-based herbicides?, J Epidemiol Community Health doi:10.1136/jech-2016-208463

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John Peterson Myers, Michael N. Antoniou, Bruce Blumberg, Lynn Carroll, Theo Colborn, Lorne G. Everett, Michael Hansen, Philip J. Landrigan, Bruce P. Lanphear, Robin Mesnage, Laura N. Vandenberg, Frederick S. vom Saal, Wade V. Welshons and Charles M. Benbrook. (2016) Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement. Environmental Health 15:19
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Br J Nutr. 2016 Mar;115(6):994-1011. doi: 10.1017/S0007114515005073. Epub 2016 Feb 16.

Philip Landrigan, Charles Benbrook. "GMOs, Herbicides, and Public Health," *New England J. Medicine* 373 (8): 693-695, August 20, 2015.

Marcin Baranski, Dominka Srednicka-Tober, Nikolaos Volakakis, Chris Seal, Roy Sanderson, Gavin B. Stewart, Charles Benbrook, Bruno Biavati, Emilia Markellou, Charilaos Giotis, Joanna Gromadzka-Ostrowska, Ewa Rembiałkowska, Krystyna Skwarło-Son, Raija Tahvonen, Dagmar Janovska, Urs Niggli, Philippe Nicot and Carlo Leifert, "Higher antioxidant and lower cadmium concentrations and lower incidence of pesticide residues in organically grown crops: a systematic literature review and meta-analyses," *British Journal of Nutrition*, http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=9289221&fulltextType=RA&fileId=S0007114514001366 (2014).

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Educating the Next Generation of Food and Agricultural Professionals (1987)
Regulating Pesticides in Food: The Delaney Paradox (1987)
Designing Foods: Animal Product Options in the Marketplace (1988)
Understanding Agriculture: Education in the Secondary Schools (1988)
Alternative Farming (1989)
Investing in Research: A Proposal to Strengthen the Agricultural, Food, and Environmental System (1990)
Pesticides in the Diets of Infants and Children (1993, started in 1989)
Soil and Water Quality: An Agenda for Agriculture (1993, started in 1988)

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# Appendix B

# EPA Rankings of the Most Heavily Used Pesticides in the U.S. Agricultural Sector: 1987-2012

## Glyphosate's Rise to theTop -- EPA Rankings of the Top Pesticides by Year in the U.S. Agricultural Sector, 1987-2001 ("Range" is in million pounds active ingredient applied) (see "Notes")□

| Active Ingredient | Type | 1987 | | 1993 | | 1995 | | 1997 | | 1999 | | 2001 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Rank | Range | Rank | Range | Rank | Range | Rank | Range | Rank | Range | Rank | Range |
| **Glyphosate** | H | 17 | 6-8 | 11 | 15–20 | 7 | 25–30 | 5 | 34-38 | 2 | 67-73 | 1 | 85-90 |
| **Atrazine** | H | 1 | 71-76 | 1 | 70–75 | 1 | 68–73 | 1 | 75-82 | 1 | 74-80 | 2 | 74-80 |
| **Metam Sodium** | Fum | 15 | 5-8 | 8 | 25–30 | 3 | 49–54 | 3 | 53-58 | 3 | 60-64 | 3 | 57-62 |
| **Metolachlor-S** | H | | | | | | | | | 12 | 16-19 | 9 | 20-24 |
| **Acetochlor** | H | | | | | 11 | 22–27 | 7 | 31-36 | 4 | 30-35 | 4 | 30-35 |
| **Dichloropropene** | Fum | 4 | 30-35 | 6 | 30–35 | 5 | 38–43 | 6 | 32-37 | 11 | 17-20 | 8 | 20-25 |
| **2,4-D** | H | 5 | 29-33 | 7 | 25–30 | 6 | 31–36 | 8 | 29-33 | 6 | 28-33 | 5 | 28-33 |
| **Trifluralin** | H | 6 | 25-30 | 9 | 20–25 | 10 | 23–28 | 10 | 21-25 | 9 | 18-23 | 12 | 12-16 |
| **Propanil** | H | 13 | 7-10 | 15 | 7–12 | 17 | 6–10 | 22 | 6-8 | 18 | 7-10 | 17 | 6-9 |
| **Dicamba** | H | 23 | 4-6 | 16 | 6–10 | 18 | 6–10 | 16 | 7-10 | 22 | 6-8 | 24 | 5-7 |

Notes: " H" is herbicide; and, "Fum" is fumigant. (—) indicates that the pesticide was not one of the 25 most commonly used pesticides in the given year. Data does not include sulfur and petroleum oil.

Source: Data from U.S. Environmental Protection Agency Pesticide Industry Sales and Usage Reports, accessible at https://www.epa.gov/pesticides/pesticides-industry-sales-and-usage-2006-and-2007-market-estimates

## Glyphosate Stays at the Top -- EPA Rankings of the Top Pesticides by Year in the U.S. Agricultural Sector, 2001-2012

| Active Ingredient | Type | 2001 | | 2003 | | 2005 | | 2007 | | 2009 | | 2012 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Rank | Range | Rank | Range | Rank | Range | Rank | Range | Rank | Range | Rank | Range |
| **Glyphosate** | H | 1 | 85-90 | 1 | 128-133 | 1 | 147-167 | 1 | 170-190 | 1 | 209-229 | 1 | 270-290 |
| **Atrazine** | H | 2 | 74-80 | 2 | 75-80 | 2 | 66-76 | 2 | 70-80 | 2 | 29-69 | 2 | 64-74 |
| **Metam Sodium** | Fum | 3 | 57-62 | 3 | 45-50 | 3 | 36-46 | 3 | 48-58 | 3 | 30-40 | 6 | 30-40 |
| **Metolachlor-S** | H | 9 | 20-24 | 6 | 28-33 | 5 | 25-35 | 4 | 27-37 | 6 | 24-34 | 3 | 34-44 |
| **Acetochlor** | H | 4 | 30-35 | 5 | 30-35 | 6 | 24-34 | 5 | 25-35 | 7 | 23-33 | 7 | 28-38 |
| **Dichloropropene** | Fum | 8 | 20-25 | 7 | 20-24 | 4 | 28-38 | 6 | 24-34 | 4 | 27-37 | 4 | 32-42 |
| **2,4-D** | H | 5 | 28-33 | 4 | 30-35 | 7 | 21-31 | 7 | 22-32 | 5 | 24-34 | 5 | 30-40 |
| **Trifluralin** | H | 12 | 12-16 | 11 | 8-10 | 14 | 6-10 | 17 | 4-8 | 18 | 3-7 | 19 | 3-7 |
| **Propanil** | H | 17 | 6-9 | 18 | 5-7 | 18 | 3-7 | 18 | 3-7 | 17 | 3-7 | 17 | 3-7 |
| **Dicamba** | H | 24 | 5-7 | | | 22 | 1-5 | — | 1-5 | 25 | 1-5 | 18 | 3-7 |

Notes: " H" is herbicide; and, "Fum" is fumigant. (—) indicates that the pesticide did not make the 25 most commonly used pesticides ranking in the given year. Data does not include sulfur and petroleum oil.

Source: Data from U.S. Environmental Protection Agency Pesticide Industry Sales and Usage Reports, accessible at https://www.epa.gov/pesticides/pesticides-industry-sales-and-usage-2006-and-2007-market-estimates

# Appendix C

# Data Sources and Methods Used to Compare the EPA and IARC Assessments of Glyphosate and GBH Genotoxicity

**Data Sources and Methods Used to Compare the EPA and IARC Assessments of Glyphosate and GBH Genotoxicity**

- Section 5.3 of the September 2016 EPA evaluation of glyphosate oncogenicity includes seven tables setting forth the studies the agency considered in the following areas:
- Table 5.1. In vitro Test for Gene Mutation in Bacteria: Glyphosate Technical (hereafter Bacterial Reverse Mutation Studies);
- Table 5.2. In vitro Mammalian Gene Mutation Assays: Glyphosate Technical;
- Table 5.3. In vitro Tests for Chromosomal Aberrations in Mammalian Cells -- Glyphosate Technical;
- Table 5.4. In vitro Tests for Micronuclei Induction in Mammalia Cells -- Glyphosate Technical;
- Table 5.5. In Vivo Tests for Chromosomal Aberrations in Mammals -- Glyphosate Technical;
- Table 5.6. In Vivo Tests for Micronuclei Induction in Mammals -- Glyphosate Technical; and
- Table 5.7. Assays for Detecting Primary DNA Damage -- Glyphosate Technical (hereafter DNA Damage).

Each of these seven tables reports the Test/Endpoint; Test System; Route of Administration; Doses/Concentration; Test Material Purity; Results; References; and, Comments. "Results" typically are "positive" or "negative," and sometimes specify the conditions under which a positive response was reported (e.g., "Negative +/- S9"; "Positive, Statistically significant [$p<0.05$] increase in MN at 15 and 20 mg/l").

The information in these tables was moved into an Excel workbook, in which the following data were recorded: Year, Author, Result, Glyphosate (form when reported), Formulated GBH (if applicable), AMPA, Surfactants, Monsanto Study (Yes/No), Other Registrant, Regulatory (done by any registrant), Public Literature, and Comments. Summary statistics by type of genotoxicity test and assay system were calculated for studies on pure glyphosate and formulated GBHs.

For regulatory studies, public literature studies, and all studies, the number of studies, number of positives, and percent positive were calculated. A similar Excel workbook was constructed from all glyphosate-related genotoxicity studies cited in Volume 112 of the IARC Monograph series in "Section 4.2 Mechanisms of carcinogenesis." The IARC Working Group organized its assessment of genotoxicity data in six tables:

- Table 4.1 Genetic and related effects of glyphosate in exposed humans;
- Table 4.2 Genetic and related effects of glyphosate, AMPA, and glyphosate-based formulations in human cells in vitro;
- Table 4.3 Genetic and related effects of glyphosate, AMPA, and glyphosate-based formulations in non-human mammals in vivo;
- Table 4.4 Genetic and related effects of glyphosate, AMPA, and glyphosate-based formulations in non-human mammalian cells in vitro;

- Table 4.5 Genetic and related effects of glyphosate, AMPA, and glyphosate-based formulations in non-human mammalian systems in vivo; and
- Table 4.6 Genetic and related effects of glyphosate and glyphosate-based formulations on non-human mammalian systems in vitro.

Each of the above six tables covers studies done on glyphosate technical, as well as any studies conducted using a formulated GBH. A few studies testing the primary glyphosate metabolite AMPA are also included in the IARC tables.

For these six IARC tables, the following information was recorded in the Excel workbook: Category of Study, Lead author and year, End-point Studied, Test/Assay, Response/Results, Comments, Cited by MON Reviews (Brusick et al. 2016; Heydens et al. 2008; Kier and Kirkland 2013; Williams et al. 2016), and Cited in the EPA September 2016 report (EPA 2016).

Summary statistics are calculated by IARC category of study and reflect the number of studies or assays considered by IARC, the number cited in one or more Monsanto-commissioned reviews, and the number cited by EPA in its September 2016 report.

# Benbrook Reliance List

## *In re Roundup Products Liability Litigation*, MDL No. 2741

## Table of Contents



**Notes:** In addition to the below listed documents, I also relied on a few documents cited in my 11/20/18 expert report that are not included in the below list.

I relied on the genotoxicity studies cited in the September 2016 EPA report evaluating glyphosate oncogenicity. I relied on the genotoxicity studies cited IARC's 2015 evaluation of glyphosate and glyphosate-based herbicide genotoxicity in the glyphosate chapter in Volume 112 of the IARC Monograph series. The majority of the published genotoxicity studies cited by EPA and/or IARC are listed in section "D. Genotoxicity Documents." Some studies cited in section B are also cited in section D.

I have conducted research and analytical work on glyphosate and Roundup herbicides for over 30 years. The below reliance list does not include many older documents that I have studied and relied on in developing my general understanding of the use, risks, and regulation of glyphosate-based herbicides.

### A. Documents With a Bates Number

| Date | Bates Number (First Page) |
|---|---|
| 9/25/15 | ACQUAVELLAPROD00009991 |
| 4/9/15 | ACQUAVELLAPROD00010215 |
| 5/14/16 | ACQUAVELLAPROD00012030 |
| 4/6/16 | ACQUAVELLAPROD00012359 |
| 1/7/16 | ACQUAVELLAPROD00014559 |
| 1/7/16 | ACQUAVELLAPROD00014559 |
| 7/30/15 | ACQUAVELLAPROD00017681 |
| 1/15/88 | MONGLY00223052 |
| 8/11/82 | MONGLY00223097 |
| 7/27/82 | MONGLY00223108 |
| 3/18/81 | MONGLY00223143 |
| 12/4/80 | MONGLY00223146 |
| 8/30/78 | MONGLY00223177 |

| | |
|---|---|
| 6/28/78 | MONGLY00223224 |
| 10/1/77 | MONGLY00223244 |
| 7/1/77 | MONGLY00223253 |
| 1/1/88 | MONGLY00223577 |
| 3/13/85 | MONGLY00233235 |
| 9/26/85 | MONGLY00233235 |
| 1/17/86 | MONGLY00233235 |
| 1/23/86 | MONGLY00233235 |
| 9/4/84 | Mongly00235097 |
| 2/26/85 | Mongly00235097 |
| 6/14/85 | Mongly00235097 |
| 12/4/85 | Mongly00235097 |
| 2/24/86 | Mongly00235097 |
| 1/1/88 | MONGLY00241308 |
| 4/14/99 | MONGLY00555372 |
| 11/19/13 | MONGLY00556464 |
| 10/5/04 | MONGLY00666980 |
| 6/8/09 | MONGLY00874417 |
| 5/31/99 | MONGLY00877463 |
| 8/3/99 | Mongly00877683 |
| 9/2/99 | Mongly00878595 |
| 4/27/00 | MONGLY00878876 |
| 4/25/02 | MONGLY00885526 |
| 4/25/02 | MONGLY00885551 |
| 7/22/97 | MONGLY00885870 |
| 6/11/02 | MONGLY00888454 |
| 5/26/00 | MONGLY00889984 |
| 1/29/10 | MONGLY00889988 |
| 9/10/01 | MONGLY00891769 |
| 11/3/99 | MONGLY00894003 |
| 11/3/99 | MONGLY00894004 |
| 11/3/99 | MONGLY00894004 |
| 9/26/12 | MONGLY00900629 |
| 10/23/15 | MONGLY00901021 |
| 7/26/04 | MONGLY00903275 |
| 5/7/15 | MONGLY00903930 |
| 5/26/99 | MONGLY00904009 |
| 6/16/99 | MONGLY00904772 |
| 6/29/99 | MONGLY00904905 |

| | |
|---|---|
| 12/6/99 | MONGLY00905088 |
| 1/3/02 | MONGLY00905589 |
| 6/11/02 | MONGLY00905650 |
| 9/15/09 | MONGLY00909017 |
| 11/18/10 | MONGLY00919381 |
| 7/8/99 | MONGLY00921330 |
| 11/24/03 | MONGLY00922458 |
| 9/13/04 | MONGLY00922461 |
| 2/13/01 | MONGLY00923065 |
| 9/23/04 | MONGLY00925905 |
| 9/28/12 | MONGLY00936725 |
| 8/13/12 | MONGLY00971543 |
| 3/14/15 | MONGLY00977035 |
| 3/14/15 | MONGLY00977253 |
| 2/5/15 | MONGLY00977267 |
| 10/10/12 | MONGLY00978886 |
| 9/27/13 | MONGLY00980032 |
| 6/27/13 | MONGLY00980158 |
| 1/22/14 | MONGLY00981878 |
| 9/2/15 | MONGLY00982099 |
| 8/21/09 | MONGLY00984228 |
| 8/22/09 | MONGLY00984228 |
| 2/20/15 | MONGLY00986901 |
| 1/7/09 | MONGLY00987424 |
| 4/28/15 | MONGLY00987755 |
| 10/15/14 | MONGLY00989918 |
| 3/17/15 | MONGLY00990361 |
| 7/1/15 | MONGLY00992949 |
| 8/28/15 | MONGLY00994301 |
| 1/13/06 | MONGLY00998682 |
| 1/4/01 | MONGLY00999235 |
| 1/6/16 | MONGLY00999487 |
| 2/9/16 | MONGLY01000676 |
| 1/7/16 | MONGLY01003669 |
| 11/12/08 | MONGLY01012203 |
| 9/16/09 | MONGLY01013201 |
| 2/27/15 | MONGLY01021648 |
| 2/12/15 | MONGLY01021708 |
| 5/11/15 | MONGLY01023968 |

| | |
|---|---|
| 10/1/85 | MONGLY01030362 |
| 11/3/15 | MONGLY01030787 |
| 11/6/15 | MONGLY01030787 |
| 11/4/15 | MONGLY01030799 |
| 9/24/15 | MONGLY01031800 |
| 12/20/12 | MONGLY01037818 |
| 6/11/10 | Mongly01041300 |
| 1/21/16 | MONGLY01041641 |
| 8/20/13 | MONGLY01045298 |
| 10/22/13 | MONGLY01051709 |
| 2/19/09 | MONGLY01061857 |
| 2/20/15 | MONGLY01087311 |
| 1/1/16 | MONGLY01090874 |
| 9/20/12 | MONGLY01096619 |
| 10/3/14 | MONGLY01147225 |
| 12/14/10 | MONGLY01155974 |
| 3/6/13 | MONGLY01159775 |
| 1/22/13 | MONGLY01174848 |
| 10/14/08 | MONGLY01179185 |
| 3/30/15 | MONGLY01179969 |
| 7/15/08 | MONGLY01182769 |
| 8/6/15 | Mongly01183933 |
| 5/14/08 | MONGLY01185826 |
| 6/22/07 | MONGLY01187777 |
| 9/9/08 | MONGLY01189468 |
| 9/21/09 | MONGLY01192115 |
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MONGLY01204377

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### C. Depositions, Deposition Exhibits, Johnson Trial Documents

All documents in the binders: “Benbrook Trial Cross Exhibits, Vol. 1 and 2,” Dewayne Johnson v. Monsanto, Superior Court of California, County of San Francisco.

All documents listed in “Dr. Benbrook - Supplemental Reliance List,” addendum to Benbrook Expert Report.

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